In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-785V

Filed: July 19, 2024

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E.A.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* * * * * * * * * * * * * * * * * * * *

E.A., *pro se*.

Alexis B. Babcock, U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION DISMISSING PETITION[1]

Roth, Special Master:

On June 30, 2016, E.A. ("petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program"),[2] alleging that a varicella vaccination administered on July 2, 2013 resulted in her development of seizure disorder, cerebral injury, Major Neurocognitive Disorder, athetosis, chorea, and/or neurologic, psychiatric, and physical impairments and other injuries that were "caused-in-fact" by the vaccination or resulted in significant aggravation to petitioner's previous seizure disorder, cerebral injury, Major Neurocognitive Disorder, athetosis, chorea, and/or neurologic, psychiatric, and physical impairment that were present to a lesser extent prior to vaccination. Petition, ECF No. 1.

On March 4, 2020, respondent filed his Motion to Dismiss "on the ground that petitioner has failed to prove that her varicella vaccination was the cause-in-fact of any of her alleged

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner had 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. This Decision originally issued on July 19, 2024, and neither party proposed redactions. Accordingly, this Decision is reissued in its original form for posting on the Court's website.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (2018) (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

injuries." Respondent's Motion to Dismiss ("Resp. Motion"), ECF No. 61. Petitioner's responses and filings will be detailed in the procedural history below.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, I find that petitioner has failed to submit sufficient proof of a vaccine related injury. Therefore, her petition must be dismissed.

I. Procedural History

Petitioner was represented by counsel when the petition was filed on June 30, 2016. Medical records, an affidavit of petitioner, and a statement of completion were filed on July 7, 2016. Petitioner's Exhibits ("Pet. Ex.") 1-14, ECF Nos. 6-8.

Following a status conference on August 3, 2016, additional medical records, letters, and affidavits were filed. Pet. Ex. 15-35, ECF Nos. 11-16.

Respondent filed his Rule 4(c) Report on April 3, 2017, stating that the case was not appropriate for compensation. ECF No. 20. Petitioner was ordered to file additional medical records, which she did on June 20 and September 7, 2017. Pet. Ex. 36-37, ECF Nos. 22, 24.

On October 16, 2017, petitioner filed a status report, advising that her counsel intended to withdraw and requested sixty days to "either obtain new counsel, dismiss the case, or otherwise advise the Court that she intends to proceed pro se." ECF No. 25.

Petitioner's counsel then filed a Motion for Attorneys' Fees and Expenses, a Motion for Extension of Time to obtain new counsel, and a Motion to Withdraw, all of which were granted. ECF Nos. 27, 29, 31-32, 34.

On April 9, 2018, petitioner filed a status report detailing a host of personal and family struggles including illness of her mother ("the mother"), whom she claimed held Power of Attorney for handling her case because of petitioner's inability to do so. An additional ninety days was requested to secure counsel, which was granted. ECF Nos. 38-41. Petitioner failed to comply with the Court's deadline and an Order to Show Cause issued on October 16, 2018. ECF No. 42.

This case was then plagued by missed deadlines, late requests for extensions of time, explanatory status reports, letters filed by the mother, claims of unreceived mail from the Clerk's office and emails from Chambers, and filings of additional evidence. Finally, an Order for respondent to file a Motion to Dismiss was issued. ECF Nos. 43-49, 51-57.

Respondent filed his Motion to Dismiss on March 4, 2020. Resp. Motion, ECF No. 61. Thereafter, due to additional personal and family hardships and illnesses precluding the mother or petitioner from responding to the Motion to Dismiss, the case was stayed from September 16, 2020 until November 16, 2020. Petitioner was then ordered to respond to the Motion to Dismiss by March 1, 2021. ECF Nos. 71-73.

On March 1, 2021 petitioner filed an "expert opinion" from Dr. Lacayo, a "Response to DOJ" with an attached "Rebuttal of Respondent's Analysis" written by the mother,[3] along with photographs of petitioner. Pet. Ex. 41-45, 51-54,[4] ECF No. 76-80.

On May 17, 2021, respondent filed an expert report and CV from Dr. Wiznitzer. Respondent's Exhibit ("Resp. Ex.") A-B, ECF No. 82. Supporting literature was filed on May 24, 2021. Resp. Ex. A Tab 1-5, ECF No. 84.

Petitioner was ordered to file a response from her expert. The order explained that "If Dr. Lacayo remains petitioner's expert in this matter, petitioner must provide a copy of Dr. Wiznitzer's report to Dr. Lacayo for consideration and response. *Any response filed by petitioner in response to this Order and Dr. Wiznitzer's report must be from Dr. Lacayo directly. Petitioner and/or petitioner's mother are not to respond to Dr. Wiznitzer's report with their personal opinions or disagreements with Dr. Wiznitzer's report; only a response from Dr. Lacayo is appropriate*." ECF No. 83 (emphasis added).

Despite clear instructions to the contrary, petitioner's mother filed a status report on July 16, 2021, in which she took issue with the content of Dr. Wiznitzer's opinions and his failure to respond to petitioner's "expert reports" or to Pet. Ex. 41-54,[5] which in part included the petitioner's response to the Motion to Dismiss, a medical history, flow sheet, immunology history and medical theories expressed by petitioner's mother, who named herself an expert being "a registered professional nurse," and scientific data and citations from public health authorities, "all meeting the Althen standard." ECF No. 85 at 2 (emphasis in original). She concluded that, since respondent failed to respond to the foregoing, it would be premature to address Dr. Wiznitzer's opinion. *Id*. at 3.

Petitioner was again ordered to file a response to Dr. Wiznitzer's report from Dr. Lacayo by October 18, 2021, along with any outstanding medical records she intended to file. ECF No. 86.

Petitioner failed to file anything further by the Court-ordered deadline and the record was closed on November 2, 2021. ECF No. 87.

The Motion to Dismiss is ripe for ruling.

II. Factual Background

A. Petitioner's Medical History

[3] The mother "represented" petitioner in this case, despite her daughter being named the pro se petitioner. The mother also provided most of petitioner's medical history to providers even after petitioner reached adulthood. From the records filed, it does not appear that petitioner has been declared incompetent or is incompetent. The mother represented that she is a registered nurse ("RN"). *See* Pro Se Report.

[4] In numbering the exhibits, petitioner skipped 46-50. She also filed two exhibits numbered 45.

[5] In the status report, the mother listed the exhibits filed with the corresponding number of the exhibit. In her list, she included Exhibits 46-50, none of which were filed into the record. *See* ECF No. 85.

In order to appreciate the conclusions reached in this matter, a detailed recital of petitioner's medical history must be included. Because this decision will be available to the public, petitioner will be referred to as E.A. and her mother, who provided most of the information and evidence, will be referred to only as "the mother".

i. Medical History Pre-Vaccination

Petitioner was born on March 30, 1997. Pet. Ex. 2 at 5. She was adopted through a closed adoption with little known about her family medical history. Pet. Ex. 15 at 7. By January 13, 1999, she had received all necessary vaccines for her age without reported event. *See generally* Pet. Ex. 34; Pet. Ex. 15 at 11-12, 14; Pet. Ex. 16 at 3.

Petitioner had a complicated childhood medical and psychological history. Hearing testing was conducted on May 19, 1999 at Cincinnati Children's Hospital. The results were normal. Pet. Ex. 33 at 27-28. In 2002, she underwent occupational therapy ("OT") evaluation and demonstrated sensory, tactile, texture, vibratory and localization disturbances, and numbness. She was five years old and only recognized about 5 letters. *Id*. at 6-21. Her treatment focused on praxis difficulties, sensory processing/modulation difficulties, postural control to promote fine motor skills, visual perception, and oculomotor skills with home programming. *Id*. at 42.

From 2004 until June 2008, petitioner received pediatric care from Montgomery Pediatrics.[6] She had learning issues and allergies and was homeschooled. Pet. Ex. 16 at 6. On August 16, 2004, petitioner underwent another audiologic assessment at the University of Florida. The mother reported petitioner to be easily distracted, inattentive to sounds with difficulty localizing sounds, confused by directions/commands, reversed letters, and intolerant of loud sounds since age 3. Pet. Ex. 18 at 3-6. The auditory evaluation revealed normal hearing sensitivity bilaterally and "no clear pattern of auditory processing disorder." *Id*. at 2, 7. The evaluation showed difficulty in maintaining attention. *Id.* It was recommended that she be assessed for attention deficit disorder ("ADD"). *Id*.

Petitioner underwent visual testing in Michigan on October 7, 2004 which showed deficits in visual tracking and binocularity with visual sequential memory 20 months below average and overall visual motor integration 15 months below average. Pet. Ex. 33 at 53. At an otolaryngology evaluation on January 8, 2005 at Cincinnati Children's Hospital, the mother reported that petitioner had sensory integration and "visual and auditory processing disorder." *Id*. at 38; *but see* Pet. Ex. 18 at 2, 7, testing showed no auditory processing disorder. The mother reported that, "psychological testing by Dr. Paul Cates (Tennessee) revealed a significant deficit in left brain function, learning disability, Attention Deficit Disorder with hyperactivity." Pet. Ex. 33 at 53. At an OT evaluation in February 2005, petitioner was noted to be a 7 year 11-month-old with significant attention deficits, increased activity level, difficulties with bilateral coordination and upper extremity speed/dexterity; difficulty with visual perception, motor tasks that required balance, and motor planning skills, all of which were expected to impact her as she gets older. *Id*. at 54.

[6] The family moved often and to different states.

The mother filled out a Health Questionnaire at a December 20, 2005 medical visit, documenting that "[s]ince the age of 2 many out of the norm things were noted…After much testing [and] learning she is now managed on a very unique plan made just for her." Pet. Ex. 15 at 7-8. The mother also reported that petitioner had an auditory and visual processing disorder, dyslexia, ADD, multiple delays, and asthma. *Id*. at 8-9.

Petitioner received all childhood vaccinations without documented event. Pet. Ex. 16 at 3. Petitioner received MMR vaccines on January 13, 1999 and June 18, 2002 and a varicella vaccine on October 30, 2008. Pet. Ex. 15 at 3. The dates of these vaccination are specifically noted because of the claims made by the mother years later regarding these vaccinations, which are detailed below.

Petitioner underwent allergy testing on April 6, 2011 for a long history of allergies. Pet. Ex. 17 at 7. The mother described petitioner as a sniffly child who was hyper and acted out when younger. When they moved to Alabama in 2005, she could not breathe and went to the ER where she was diagnosed with reactive airway disease and treated with albuterol. The trigger was unknown. *Id*. The mother reported that petitioner had hives last summer and took Zyrtec and Zantac with no hives since. Some days she had chest and throat problems and needed to take a huge breath to feel like she gets full breaths. She occasionally had shortness of breath when she sings. Skin testing was positive for dust mites, cats, dogs, and grass. *Id*. Current symptoms included nasal congestion, mouth/throat swelling, feeling of chest tightness, shortness of breath, cough with exercise, pneumonia/bronchitis, coughing spells with gagging, vomiting, and nausea. *Id*. She had just completed 8th grade with As and Bs. The examination that day was normal. *Id*. The assessment was allergic rhinitis,[7] history of chronic urticaria,[8] and shortness of breath. *Id*. at 8. Zyrtec, Zantac, Albuterol puffs, and Singulair were recommended. *Id*.

ii. Medical History Post-Vaccination

There were no medical records filed between May 2011 and petitioner's first visit in July 2013[9] with Groff Family Practice ("Groff") in Georgia. Pet. Ex. 2 at 37-43. The mother claims petitioner required no medical care between 2010 and July 2013. Pet. Ex. 35 at 5-6.

Petitioner was accompanied by her mother to her first visit at Groff on July 2, 2013. Pet. Ex. 2 at 42. She was 16 years old. *Id*. She was noted to have been adopted and had a history of asthma and allergies to dust mites and cats, cough with exertion and shortness of breath when running. She was homeschooled. *Id.* at 43. Petitioner reported "wiggling of her fingers lately, and her handwriting has apparently interfered with that." *Id*. On examination, "she [had] a little bit of motion in her hands when she [held] them out front. I don't know if that's a conversion reaction[10]

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[7] Rhinitis is inflammation of the mucous membrane of the nose. *Dorland's Illustrated Medical Dictionary* 1613 (33rd ed. 2019) [hereinafter "*Dorland's*"].

[8] Urticaria is a vascular reaction in the upper dermis, usually transient, consisting of localized edema caused by dilatation and increased capillary permeability with wheals. *Dorland's* 1981.

[9] It appears that an appointment was scheduled at Groff for October 16, 2012 but was cancelled. Pet. Ex. 2 at 48.

[10] Conversion disorder is a mental disorder characterized by conversion symptoms (loss or alteration of voluntary motor or sensory functioning suggesting physical illness, such as seizures, paralysis, dyskinesia, anesthesia, blindness, or aphonia) having no demonstrable physiologic basis and whose psychological basis is suggested by (1) exacerbation of symptoms at times of psychological stress, (2) relief from tension or inner conflicts (primary gain) provided by the

or whether she's getting athetosis[11] or developing Chorea."[12] *Id*. She was assessed as generally healthy. "She also has a history of this peculiar movement disorder which I think is reasonable to have her go on and see the Neurologist." *Id*. The mother expressed concern that petitioner was having a reaction to Zantac because she complains she feels early satiety and fullness at times. *Id*. at 43-44. Testing of stool antigen for H-Pylori was ordered. *Id*. at 44. Petitioner received the subject varicella vaccine at this visit. *Id*. at 1, 36.

Three days later, on July 5, 2013, the mother presented petitioner to Clearview Regional Medical Center Emergency Room, reporting that petitioner had a varicella vaccine 4 days ago, had a sore throat this morning with swollen uvula,[13] and a scratchy throat last night. Pet. Ex. 3 at 2. The chief complaint was noted as "Allergic Reaction-breathing difficulty." *Id*. at 10. The medical record documents, "no signs or symptoms of anaphylaxis were noted", she was in "no apparent distress", and her "[a]irway was patent mildly swollen uvula Respiratory effort is even, unlabored". *Id*. at 2, 3. She did "not display signs of respiratory distress" and there was no shortness of breath, cough, or wheezing. *Id*. at 8. A rapid strep test was positive, but a throat culture was negative. She was administered Bicillin and Solu-Medrol by injection. Pet. Ex. 2 at 29-30; Pet. Ex. 3 at 11. The discharge diagnosis was pharyngitis and strep. Pet. Ex. 3 at 6.

The mother and petitioner returned to Groff on July 12, 2013 for follow up. The mother reported that petitioner was seen in the ER for sore throat, trouble swallowing, and choking; "up to that time, she'd been just kind of feeling vaguely ill for a couple of weeks." Pet. Ex. 2 at 24. A rapid strep test was positive, she received penicillin and steroids. She also had a "little headache and a low grade fever". *Id*. Examination that day revealed some exudate on the left side of her throat, but the remainder of the exam was normal/negative. *Id*. "Persistent vague symptoms" were also documented and since the rapid strep test was positive but strep culture was negative, it was unclear whether she actually had strep. Blood work and a Mono Spot were ordered. The mother asked for a referral to Dr. McKean for petitioner's "chronic allergies". *Id*. Lab results showed mildly elevated monocytes[14] of 0.8 on a 0.1-0.7 range. *Id.* at 27. The Mono Spot test was negative. *Id.* at 28.

The mother and petitioner presented to Dr. McKean on July 16, 2013, reporting a history of asthma triggered by exercise, urticaria, and difficulty breathing when they moved to Alabama. She previously tested positive for allergies to dust mites, cats, dogs, grass, and pollen. Pet. Ex. 2 at 18. She had been taking Xopenex, loratadine, and ranitidine. *Id*. Dr. McKean noted that petitioner had Pressure Equalizing tubes placed at age 7. *Id*. at 19. The mother reported that petitioner had received a varicella vaccine on July 2, 2013, followed by breathing difficulty,

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symptoms, or (3) secondary gains (support, attention, avoidance of unpleasant responsibilities) provided by the symptoms. *Dorland's* 543.

[11] Athetosis is a form of dyskinesia marked by ceaseless occurrence of slow, sinuous, writhing movements, especially severe in the hands, and performed involuntarily. *Dorland's* 169.

[12] Chorea is the occurrence of a variety of continual, rapid, highly complex, jerky, dyskinetic movements that look well-coordinated but are actually involuntary. *Dorland's* 349.

[13] The uvula palatina is the small, fleshy mass hanging from the soft palate above the root of the tongue, composed of fibers of the levator and tensor veli palatini muscles and the musculus uvulae, connective tissue, and mucous membrane. *Dorland's* 1983-84.

[14] Monocytes are formed in the bone marrow then are transported to tissues such as the lung and liver, where they develop into macrophages. *Dorland's* 1159.

dysphonia, and enlarged uvula. She was given steroid and penicillin injections due to a positive strep test. *Id*. at 18. She then had "mood changes", urticaria on her hands and neck, and GI problems. Epstein Barre Virus testing was negative, and CBC showed elevated monocytes. The record included that "[s]he started to have a tremor about 2 months ago. She is seeing a neurologist." *Id*.; Pet. Ex. 4 at 33.

The mother and petitioner presented to neurologist Dr. Lacayo on July 18, 2013 and reported chorea like tremors, which she was born with but was worse with stress, fatigue, or heavy lifting. Pet. Ex. 5 at 13-15. Dr. Lacayo ordered testing of copper levels, ceruloplasmin, and ASO titer. She displayed laxity of the joints. *Id*. at 15. Dr. Lacayo noted the tremor to be "unremarkable" and that irregular small movements can occur due to muscle weakness, but there were no choreaform or athetotic movements. "Huntington's is quite rare but a consideration if movements progress with imbalance." He documented that petitioner had cognitive deficits, laxity of joints, and flat feet. He considered "unspecified diffuse connective tissue disease" due to laxity of her joints with suspected laxity in her airway. He agreed that cardiac testing should be done since cardiac conduction deficits can be associated with connective tissue disease. He also recommended that genetic testing be done in the future, as well as a sleep study. *Id*. Tissue disease, autoimmune mediated process, or neurodegenerative condition like Wilson's disease were included in his differential. *Id.*

Petitioner and the mother presented to Dr. Dyer on July 24 and 26, 2013, for "an updated psychological assessment to evaluate cognitive and academic functioning, particularly in the area of reading." Pet. Ex. 6 at 10. The mother reported that petitioner avoided eye contact as an infant, did not like cuddling or interactive play, was easily distracted, did not respond to pain normally, and struggled to follow direction as a young child. She met her developmental milestones on time. She takes ranitidine and loratidine for allergies. She was homeschooled for two years of pre-kindergarten in Ohio and displayed delayed comprehension of tasks. *Id*. She attended Faith Christian Academy for kindergarten with an IEP developed due to severe intellectual delay. *Id*. at 10-11. The family moved often, and she attended various schools and was homeschooled between kindergarten and 10th grade. *Id*. at 11. Public school was considered for 11th grade, but end of year testing and lack of special educational services resulted in her continuing to attend a school called Faith Academy and home schooling. Petitioner was involved in year-round education and consistently struggled, primarily in math and reading, self-direction, organization, and independence in academics. The mother described petitioner as kind but with difficulties with task persistence, frustration, and following directions; she was easily angered, defiant at times, and struggled to control negative mood. She said petitioner worries about social interaction and academic performance, and her attention and auditory processing are an issue. *Id*.

Dr. Dyer referenced petitioner's extensive testing over the years. Pet. Ex. 6 at 11-12. Dr. Dyer's testing over two days showed weak verbal memory, reading comprehension, spelling, and math skills. *Id*. at 12, 16. She was diagnosed with "Unspecified Anxiety Disorder." *Id*. at 16. Petitioner reported feelings of sadness, anger, disengagement from family and friends, and isolation, but these feelings do not significantly impair functioning. She displayed attention-based disorder, but additional testing would be required for a diagnosis. *Id*. A list of recommendations was provided, including classroom accommodations, an attention assessment, and therapy to learn coping skills. *Id*. at 16-18.

A sleep study performed in the summer of 2013 showed insomnia and essential tremors.[15] Pet. Ex. 5 at 6, 11, 12.

Dr. Lacayo conducted an EEG on January 23, 2014 which he read as "abnormal" with evidence of left hemisphere dysfunction and onset of seizure disorder in the left hemisphere. Pet. Ex. 5 at 6, 11-12, 20; Pet. Ex. 2 at 12. Dr. Lacayo documented his findings in a letter indicating a need for an MRI to evaluate for a seizure disorder. Pet. Ex. 2 at 11. The MRI was performed on January 31, 2014 and was normal. Pet. Ex. 5 at 18; Pet. Ex. 2 at 10.

On March 4, 2014, petitioner presented to Dr. Lacayo for new abnormal movements and past auditory/verbal processing impairment. Pet. Ex. 5 at 11. The mother reported changes in petitioner's behavior with increased rebellion, outbursts, and problems with rules which began after the varicella vaccine. Pet. Ex. 2 at 6; Pet. Ex. 5 at 11. Dr. Lacayo's assessment was possible seizures, left hemisphere dysfunction, anxiety, learning disorders, and attention deficit disorder with associated tics. Pet. Ex. 2 at 8. He wrote that he did not know whether the vaccine directly caused these symptoms, "but the timing of such with her seems to have aggravated her condition, with history of the same in the past. I would hold vaccines as much as possible." *Id*.

The mother presented to Groff without petitioner on March 12, 2014 and wanted to discuss Dr. Lacayo's opinion of a relationship between the varicella vaccine and petitioner's symptoms. The Groff medical record documents, "She was trying to explain several things about what Dr. Lacayo was doing and that [petitioner's] issues were related to the Varicella vaccine she received in July 2013. Dr. Lacayo's note from 3/4/14 clearly states that the relationship between [petitioner's] issues and the vaccine are not known." The mother became argumentative and was asked to leave the office. Pet. Ex. 2 at 3, 5. The record documents that a staff member at Groff then called Dr. Lacayo who advised that "there is no way to determine the relationship between the vaccine and [petitioner's] symptoms." Dr. Lacayo said that petitioner had objective findings on EEG, and he was treating her to see if there were any changes. Dr. Lacayo stated he advised the mother "that [petitioner] may need a psychiatric evaluation to make sure there are no other conditions that may be contributing to the problems." Finally, Dr. Lacayo stated his only recommendation to the mother regarding the vaccine was to file a report with the vaccine registry of a possible reaction, if she chose to do so. *Id*. at 5. The Groff practice advised the mother to find a new PCP. *Id*. at 3.

Dr. Lacayo conducted another EEG on March 24, 2014, which he read as abnormal and supportive of a seizure disorder but improved from her prior EEG. Pet. Ex. 5 at 17.

On April 5, 2014, petitioner's parents had petitioner admitted to Ridgeview Institute until April 14, 2014 as a "last resort" for her anger and uncontrolled outbursts. Pet. Ex. 7a at 4, 6. The parents reported that petitioner's behavior issues began in September 2013, had intensified since, and were suspected to be associated with a varicella vaccine. The mother reported a similar episode of unexplained behavior following petitioner's receipt of her first varicella vaccine. *Id*. at 6.

[15] An essential tremor is a hereditary tremor with onset at varying ages, usually at about 50 years of age, beginning with a fine rapid tremor of the hands, followed by tremor of the head, tongue, limbs, and trunk; it is aggravated by emotional factors and is accentuated by volitional movement. *Dorland's* 1927.

Petitioner however, reported "[s]ignificant current discord" with parents, which included her parents locking her out of the house and police involvement after she presented to work with an injury following an "altercation" with the mother. *Id*. She reported moderate anxiety, obsessive thoughts, compulsive behaviors, feelings of hopelessness, trouble sleeping and eating, and mood swings. *Id*. at 6-7. She wanted to find her biological parents. *Id*. at 104. The discharge summary described petitioner as polite and cooperative without any out-of-control behavior noted on admission or on the unit. *Id*. at 3. "She continue[d] to be sad and ha[d] difficulty expressing her feelings, especially anger and impulse control issues. Anger is secondary to CNS dysfunction." *Id*. Consistent follow up with outside counselling was strongly recommended. *Id*. at 15.

The mother and petitioner presented to Eastern Atlanta Behavioral Health ("Behavioral Health") as a new patient on April 16, 2014. Her history was reported as episodes of staring, obsessive thinking, erratic behavior, tremors, and temporal lobe seizures. She was recently admitted to Ridgeview for "seizure induced personality changes". Pet. Ex. 8 at 16. The mother reported that the episodes began at age 5 after a chicken pox vaccination.[16] *Id*. The assessment was severe mood swings, possibly caused by seizures, bipolar disorder, or borderline personality disorder. *Id*. at 17.

A prolonged EEG performed at Emory on April 28, 2014 was normal when compared to prior EEGs. Left hemisphere dysfunction had improved overall. There were brief episodes of generalized slowing, which were nonspecific and possibly related to fatigue. There were no abnormal EEG patterns associated with reported episodes of emotional outbursts, alteration in awareness, and wandering, "indicating a non-epileptic cause" for those reported events. Pet. Ex. 5 at 16.

The mother presented to Behavioral Health on April 29, 2014 without petitioner and advised that petitioner was having 30-second seizures and pathologically lying with personality switches she did not remember. The mother reported a chicken pox booster in July 2013 and that she believed that petitioner had developmental delays from vaccinations that "last for a couple of years." Her MRI was normal. Pet. Ex. 8 at 15.

Petitioner presented to Behavioral Health for follow up appointments on May 6, 2014, May 20, 2014, and June 19, 2014. She was taking Lamictal and Ativan and reported doing well. Pet. Ex. 8 at 10-14.

At a July 10, 2014 visit with Dr. Lacayo, petitioner was noted to be a well-nourished 17-year-old with a normal examination. Her hand tremor and athetoid movements had improved and she was negative for both Wilson's and PANDAS. Pet. Ex. 5 at 7. Dr. Lacayo's assessment was possible seizures, anxiety disorder, ADD with tics, and transient alteration of awareness. *Id*.

Petitioner was presented to Dr. Helmers,[17] an epileptologist at Emory Health ("Emory"), on July 14, 2014 for an initial evaluation of "new onset partial seizures with most likely left temporal focus" and a history of reading problems and psychiatric issues. Pet. Ex. 9 at 1; Pet. Ex. 5 at 46-47. The history was reported by the mother and petitioner and included an onset of seizures

[16] Petitioner received an MMR vaccine at age 5—not a varicella. Pet. Ex. 15 at 3.
[17] Unfortunately, Dr. Helmers has since passed away.

with "staring off" over the last 6-12 months with no such prior events. Pet. Ex. 9 at 2. These events were without warning and lasted for a few seconds. An EEG showed left temporal sharps, an AEEG was reported as unsuccessful, and an MRI was normal. *Id*. She has been taking Lamictal for psychiatric issues and had reading comprehension problems. She was a rising Senior on A/B honor roll and wanted to major in the performing arts. "Mom says she hmet (sic) developmental milestones normally." *Id*. The mother reported her first seizure was at age 16 without fever but never diagnosed; her most recent seizure was four days ago. *Id*. Her seizures appear in clusters and are triggered by lack of sleep and stress. *Id*. Examination that day was normal. *Id*. at 4-5. A 3T epilepsy protocol MRI was ordered to assess for left temporal pathology/etiology. *Id*. at 5. A psychiatrist knowledgeable about epilepsy and psychiatric disorders was recommended. *Id*.

Petitioner returned to Dr. Dyer on August 8 and 20, 2014, with reported decline in emotional behavior over the past year. Pet. Ex. 6 at 1. The mother reported that petitioner suffered physiological and psychological changes and cognitive decline following rounds of vaccinations at ages 5, 6, and 16. *Id*. at 2. She further reported that Dr. Lacayo believed petitioner had a seizure disorder that may be related to vaccination. She reported that petitioner had received a varicella booster in July 2013, was taken to the ER for respiratory distress, and developed a tremor shortly thereafter with psychological and cognitive issues over the next several months. She had a sleep study at Emory but the doctors were unable to agree on the cause of her unusual patterns of brain activity but were considering autoimmune encephalitis[18] and Wilson's disease, which was previously ruled out but being retested. *Id*. She was taking Lorazapam since August 2014 to stabilize her mood and regulate brain activity. She had received several potential diagnoses "including Dissociative Identity Disorder, Temporal Lobe Epilepsy with Behavioral Changes, Vaccine Injury/Brain Injury, Rapid Cycling Bipolar Disorder, and Borderline Personality Disorder, as provided by [the mother]." *Id*. According to Dr. Dyer, testing that day reflected a decline in cognitive and academic functioning and as described by the mother, "there is evidence that suggests a causative link between vaccinations and periods of cognitive decline, [but] such a diagnosis is not available per diagnostic codes listed in the DSM-5." *Id*. at 5-6.

Petitioner presented to Behavioral Health on September 15, 2014, reporting that she had done well over the summer but recently had a "meltdown" and "other odd behaviors" and her parents called the police. Pet. Ex. 8 at 10. She was to continue current medications and therapy. *Id*. at 11.

Petitioner was returned to Emory on October 14, 2014. Pet. Ex. 9 at 7. The mother provided the history since their last visit which included rapid eye flutter, vibrations, and tremor during an EEG, and an IQ drop to "first grade level". *Id*. Although the record appeared to repeat the history provided on the July 14, 2014 visit, there were a few changes. For example, at the July 14, 2014 visit, there were no epilepsy risk factors noted and a list of dates of developmental milestones was provided. *Id*. at 2. At the October 2014 visit, epilepsy risk factors now included that she "had the same psychiatric and academic alteration at age 5 and neuro development therapy was started and by age 11 she was back on track." *Id*. at 8. In July 2014, her seizures were without warning and lasted a few seconds with no pattern. Her psychiatric symptoms were rare while on Lamictal. *Id*. at 2. In October 2014, her seizures were described as involving behavioral arrest and alteration in awareness, lasting more than 30 seconds, occurring a couple times per day, and followed by a

[18] Encephalitis is inflammation of the brain. *Dorland's* 605.

couple of minutes of postictal confusion. *Id*. at 8. Petitioner and the mother then detailed numerous events[19] they claimed occurred during petitioner's long-term video EEG in September 2014, but the record showed no EEG correlation concluding the reported episodes "are not epileptic in origin." *Id*. at 9. The focal slowing seen on EEG was also determined to be "non specific in etiology." *Id*. A 3T MRI was normal. *Id*.

A record dated December 8, 2014, documented that petitioner was under medical care for medically refractory symptomatic generalized epilepsy. There were no neurological contraindications to the patient having surgery as scheduled, but they "highly recommend[ed]" that no Demerol be given.[20] Pet. Ex. 9 at 39.

On December 15, 2014, petitioner was presented to Emory for examination by neurologist Dr. Silver. The mother provided a history of a previously healthy 17-year-old who had learning difficulties when she was six and was diagnosed with autism spectrum disorder[21] but "overcame this" with therapy. Pet. Ex. 9 at 13. She was a successful high school student with good grades and enjoys singing. *Id*. The mother reported bilateral hand tremors since last fall which worsened with writing or lifting and occasionally had larger "jerky" movements when playing the piano. Dr. Lacayo referred to them as tremors, but they looked like athetosis. All testing was negative. The mother further reported that a January 2014 EEG showed "focal slowing and electrographic seizures per outside read." Petitioner was started on Lamictal, titrated up, and the athetosis improved. *Id*. Petitioner had a long EEG at the hospital to evaluate for possible seizure activity. She was taken off her medication for the testing resulting in eye jittering, eye twitching, emotional instability, and episodes of staring off. *Id*. at 14. However, the EEG did not correlate with any of these behaviors. The mother added that petitioner had "extreme personality changes" and difficulty with schoolwork in December 2013. Her reading spontaneously decreased to 1st grade level. She went from an A/B honor student in 9th and 10th grade in private school to having to be homeschooled senior year due to failing performance. *Id*. She was admitted to Ridgeview in April 2014 and started on Ativan for borderline personality disorder. *Id*. Dr. Silver's examination was normal/negative, as was an MRI performed. *Id*. at 16-17. Dr. Silver wrote that all testing thus far was negative/normal. *Id*. at 17. He ordered additional testing for Wilson's disease because it was "the main diagnostic possibility here for an organic disorder. . . Psychogenic[22] certailnly (sic) is a possibility." *Id*. at 18.

Petitioner and her mother presented to Behavioral Health on February 18, 2015 and reported that the testing at Emory was inconclusive. She was stable that day but still had episodes of decreased cognitive function. Pet. Ex. 8 at 8. They discussed a gluten free diet. *Id*. at 9.

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[19] They claimed that, during the EEG, petitioner's arms vibrated and were tremulous, her psychiatric/emotional state changed, she had unusual eye movements, she had right arm twitching and bilateral feet twitching, was weak in the head, and had eye blinking and facial twitching. Pet. Ex. 9 at 8.

[20] It is unclear when and based on what testing petitioner was diagnosed with medically refractory symptomatic generalized epilepsy or what surgery was being referred to. There were no records filed reflecting this.

[21] A letter submitted by Dr. Cates states that, at age 5 or 6, petitioner exhibited signs of being on the autism spectrum during an academic assessment to develop an IEP. Pet. Ex. 26. However, there are no contemporaneous records to corroborate petitioner's autism diagnosis.

[22] Psychogenic refers to symptoms that are produced or caused by psychological factors. *Dorland's* 1525.

Petitioner returned to Dr. Silver on March 26, 2015 at which time, Dr. Silver wrote that petitioner had a history of complicated psychological and neurological symptoms, but it was unclear whether her problems were "organic". Pet. Ex. 9 at 19. The only subjective finding was an EEG showing bilateral independent temporal slowing, which was sharply contoured but not epileptiform. *Id*. All testing has been normal. Her psychiatrist reportedly thinks her issues are neurological—not psychiatric. However, "[d]ifferent impressions had come from psych before including the rapid-cycling bipolar and borderline personality disorder." *Id*. According to Dr. Silver, "[o]ne has to wonder if her family did not have the resources and knowledge that they have, if this case would have been diagnosed as a mental illness and the neurological aspects of this wouldn't be addressed. . . We spent a lot of time talking about vaccines and gluten and other things that her mother is concerned may be playing a role." *Id*. at 23. Dr. Silver recommended she be seen by the epilepsy department and noted that Lamictal "clearly helped her but of course this has great psychiatric benefits as well". *Id*. He recommended further psychiatric treatment. *Id*.

On May 8, 2015, the mother again presented to Behavioral Health without petitioner to discuss several issues. The mother had emailed Behavioral Health the day before detailing recent problems including that petitioner talked "as if everything is about her", "insights (sic) chaos", and incites fear in her family members. Pet. Ex. 8 at 5-6. The mother believed petitioner needed intense counseling and the parents were considering sending her to Mercy Ministries, a six-month inpatient center. *Id*. at 6-7.

Petitioner then presented to Behavioral Health on May 21, 2015 reporting "a lot of depression." She refused medication. She was noted to be evasive and externalizing. Pet. Ex. 8 at 3. The assessment was worsening depressive symptoms. *Id*.

Petitioner and the mother presented to Dr. McKean on June 3, 2015. She had congestion and frequent sniffling for which she took cetirizine every night. The mother reported that petitioner's tremors were exacerbated and "she was found to have a neurologic injury with absence seizures and psychotic reactions." Pet. Ex. 4 at 22; Pet. Ex. 19 at 5. The examination that day was normal. Pet. Ex. 19 at 7. She had no restriction or airflow obstruction. *Id*. at 9. She was instructed to continue her allergy medications. *Id*. at 8.

Petitioner and her mother returned to Dr. Lacayo on June 5, 2015. It had been a year since her last visit. Inpatient care for depression was being considered. Pet. Ex. 5 at 1-2. Long term monitoring at Emory showed no overt seizures. *Id*. at 2. Her tremors had improved. She graduated this year. She was now being evaluated for immune issues. She saw an allergist for breathing issues. *Id*. Examination on that day was normal/negative but for reduced reflexes. *Id*. at 2-3. Dr. Lacayo wrote, "[i]t is unclear how much psychological issues are contributing to [her] spells." *Id*. at 3. In a separate handwritten form, Dr. Lacayo documented a normal examination including a normal, intact neurological examination. *Id*. at 39.

Petitioner and her mother returned to Dr. Silver on June 11, 2015. She was now 18 years old with a constellation of psychological and neurological symptoms. It was still unclear if her symptoms were due to an "organic" cause because all testing was negative/normal. Pet. Ex. 9 at 25. Dr. Silver wrote that an outside EEG was read to have more concerning findings than what was found on testing by Emory epileptologist Dr. Helmers. *Id*. She was seeing a psychiatrist, but

the parents planned to send her to residential care through Mercy Ministries. *Id*. "The issue of whether she actually had seizures is still unclear." *Id*. at 26. Dr. Silver wrote, "[o]n the urging of her mother…exhaustive workup for causes" had been done with the most likely causes excluded. *Id*. at 29. Her acetylcholine receptor ("AChR")[23] came back positive with low titers, but she has no symptoms of myasthenia gravis ("MG").[24] Nonetheless, "[h]er mother has seen this and is concerned that she could have myasthenia." *Id*. Her tremors appear to be mild essential tremors and not an important feature of her case. *Id*. Dr. Silver's plan was for her to be seen at Emory epilepsy, have the outside EEG read at Emory, and consider repeating AchRAb tests adding anti-thyroglobulin testing. *Id*. at 30. Dr. Silver further noted that the "mother [is] insistent that there is organic cause to her symptoms but nothing is turning up. It would have been better to have worked her up when she had initial psych problems. [N]ow story is very convoluted and she has such mild problems compared to before." *Id*.

Petitioner was referred by her psychiatrist to Heather Richardson, Psy.D. on June 10, 2015 for psychological evaluation. Pet. Ex. 13 at 3. The mother provided a history of temporal lobe epilepsy, but Dr. Richardson noted that "no documentation has been provided to support the diagnosis." *Id*. The mother further reported changes in petitioner's personality including being combative, having negative computer conversations, interacting with peers she was asked not to, and rebelling for which the police have been called. Petitioner reported feeling lonely, isolated, and distressed by the nature of her relationships with her family. *Id*. Testing revealed low frustration tolerance and limited coping strategies. *Id*. at 4. She had elevated depression scores consistent with her reports. Her profile suggested physical manifestations of her depressive symptoms, consistent with "her frequent doctor's visits, prompted by her mother who is seeking an organic explanation for her emotional and behavioral difficulties." *Id*. Continued private and group therapy was recommended. *Id*. Petitioner attended sessions with Dr. Richardson through September 10, 2015. *Id*. at 2. Petitioner traveled alone over the summer for several weeks and returned in a positive mood. She had begun to attend college classes, and Dr. Richardson documented that petitioner had been making progress in their sessions. *Id*. However, in a January 18, 2016 note, Dr. Richardson documented that petitioner and her father showed up to the office for an unscheduled appointment, then petitioner "simply did not return after" so her sessions were informally terminated. *Id*. at 1-2.

The mother provided the outside EEG which she claimed showed seizure activity to Emory for review. Pet. Ex. 9 at 31-32, 40. However, the video EEG from September 2014 at Emory showed no EEG correlate with the events petitioner reported. *Id*. at 33-34, 40.

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[23] The AChR antibody blocks neuromuscular transmission by interfering with the binding of ACh to AChR along the muscle membrane, which prevents muscle contractions. The acetylcholine receptor antibody test is used to diagnose myasthenia gravis and to monitor patient response to immunosuppressive therapy. The measured titer does not correspond well with the severity of MG symptoms, though. It is important to note that false positives can occur in patients for reasons including the use of muscle relaxant drugs or penicillamine. Kathleen Deska Pagana, PhD, RN & Timothy J. Pagana, MD, FACS, *Mosby's Manual of Diagnostic and Laboratory Tests* 22-23 (6th ed. 2018).

[24] Myasthenia gravis is an autoimmune disease of neuromuscular function due to the presence of antibodies to acetylcholine receptors at the neuromuscular junction; characteristics include muscle fatigue and exhaustion that fluctuates in severity, without sensory disturbance or atrophy. It may be restricted to one muscle group or become generalized with severe weakness and sometimes respiratory insufficiency. It may affect any muscle of the body, but especially muscles of the eyes, face, lips, tongue, throat, and neck. *Dorland's* 1197.

On August 3, 2015, petitioner and the mother returned to Emory. The record documents that "mom states 7/2013 had a varicella booster and 3 days later had an anaphylactic reaction." Soon thereafter, petitioner started having tremors/choreoathetosis. About a month later, psychiatric symptoms began which eventually required her to be hospitalized multiple times. She developed insomnia and school performance worsened. Multiple EEGs were purportedly interpreted as abnormal and showing epileptiform activity, and she was started on Lamictal in early 2014. Pet. Ex. 9 at 33. She has had extensive workup, all of which was unremarkable. *Id*. at 34. The plan was to stay on Lamictal since she felt better on it. *Id*. at 37. A neuroimmunology evaluation at the University of Pennsylvania was recommended since her symptoms "may be related to the varicella booster." *Id*.

Petitioner and her mother presented to Dr. McKean on August 19, 2015 at which time the mother reported that petitioner was examined by the Chief of Neurology at Emory who did not feel she had epilepsy. She was found to have antibodies to acetylcholine receptor, but they did not believe she had myasthenia gravis. She was fatigued with increased tremor and weakness after exercising. Pet. Ex. 4 at 12, 16. She worked as an aide at a school for special needs children. She had no asthma symptoms. *Id*. at 12. Spirometry was stable. *Id*. at 21.

Laboratory tests performed that day showed that she had sufficient protective antibodies for tetanus toxoid and diphtheria but was negative for Varicella Zoster antibodies (IgM and IgG[25]). Pet. Ex. 14 at 4-5. She had a high level of AChR blocking and binding antibodies, which showed borderline myasthenia gravis, and tested positive for Human Herpes Virus 6 ("HHV-6").[26] *Id*. at 1, 4.

Petitioner returned with the mother to Dr. McKean on September 3, 2015 and it was reported that she had constant fatigue requiring at least a two hour nap daily. She was more irritable, emotional, and hostile over the past two weeks. She had chronic nasal congestion and rhinorrhea. Pet. Ex. 4 at 9.

Petitioner was referred to Dr. Rivner, and presented on October 21, 2015. The history provided included receipt of a vaccine during the summer of 2013 with difficulty breathing and swallowing three days later and a swollen throat and uvula thought to be strep, which was treated with penicillin and steroids. She then developed a bilateral arm tremor and was diagnosed with athetosis. Pet. Ex. 12 at 65. Testing for Wilson's disease was negative. Around December 2013, she "started to act lethargic and strange" and had staring spells. EEG showed left-sided slowing, but MRI was normal. Lamictal was started in January 2014 and titrated up in May. She was admitted for psychiatric issues. She had "mental status problems", did poorly in school, and was thought to have autoimmune encephalopathy.[27] She had a positive AChR on paraneoplastic panel. *Id*. She was seen at Emory taken off Lamictal but had seizures so it was restarted. She had diplopia and her eyesight was worsening. Her neck gets tired when she has tremors. Her writing has

[25] IgA, IgG, and IgM are all immunoglobulins that function as antibodies. Certain classes of antibodies can trigger other processes when bound to antigen: IgM and IgG activate the classic complement pathway, IgA and IgG activate the alternative pathway, and IgM, IgG1, and IgG3 act as opsonins, triggering phagocytosis of the bound antigens by macrophages and neutrophils. *Dorland's* 908-09.

[26] The human herpes virus 6 is a virus of the genus *Roseolovirus* that is the etiologic agent of exanthema subitem. Most healthy adults carry the virus and are asymptomatic, but infection results in lifelong persistence. *Dorland's* 843.

[27] Encephalopathy refers to any degenerative disease of the brain. *Dorland's* 608.

worsened. *Id*. Following examination, Dr. Rivner's impression was possible autoimmune encephalitis manifested by seizures, athetosis, personality changes, and dementia; abnormal AChR, CMV IgG, HHV6-possibly autoimmune etiology; clinically, no significant myasthenia gravis. *Id*. at 70. Additional testing was ordered. *Id*. at 71. EMG/Nerve conduction testing was normal. *Id*. at 75-76.

At her November 11, 2015 visit at Behavioral Health, the mother reported that petitioner was diagnosed with myasthenia gravis and was being tested for NMDA receptor antibody encephalitis. Pet. Ex. 8 at 1. She was psychologically stable and had fair attention, concentration, and productivity at school. She had no mania, mood swings, anxiety, hallucinations, or delusions. *Id*.

MRIs performed on December 11, 2015 were normal. Pet. Ex. 12 at 55, 57. A lumbar puncture performed on December 23, 2015 and sent to the University of Pennsylvania did not show antibodies to "any component of the autoimmune encephalitis". Pet. Ex. 12 at 37, 49.

Petitioner and her mother then presented to a new neurologist, Dr. Dabas, on January 12, 2016 to rule out autoimmune encephalitis. She was reportedly referred to Dr. Dabas for chorea of both hands that started 2 years ago after receipt of a varicella vaccine booster. Following receipt of the varicella vaccine she developed a swollen uvula and was treated for an allergic reaction or strep with penicillin and steroids. She also had breathing problems that lasted for a week. She began having chorea of the hands and behavioral issues. Pet. Ex. 12 at 24. She was noted to have staring spells and was diagnosed with seizures following EEG. Lamictal was started which improved her staring, but her behavior continued to worsen. A psychiatrist increased the Lamictal which helped. *Id*. Her school performance declined, and she was positive for ACHR but clinical evaluation did not show myasthenia gravis. *Id*. at 25. She reportedly had similar behavioral problems at age 5 after her first dose of varicella[28] and "likely had autism spectrum disorder. She had sensory therapy at that time which as per mother has returned." *Id*. Her levels of IgA and IgM were low, but IgG levels were normal. *Id*. The diagnosis that day included memory decline, post-vaccine behavior problems, and chorea. *Id*. at 28. She was to undergo CT of the abdomen and pelvis to rule out tumor, a neuropsychiatric evaluation, and have her PTH and ionized calcium levels checked. *Id*. A CT performed on January 27, 2016 was negative/normal. *Id*. at 19.

One week later, petitioner and her mother presented to Dr. Morgan who wrote an addendum to Dr. Dabas's visit note to include that according to mother, petitioner had a history of sensory issues and is on the autism spectrum. Pet. Ex. 12 at 28. The mother then reported to Dr. Morgan that petitioner had behavioral and cognitive changes at age 5, which did not resolve until age 10 and presented again at age 16 after the varicella vaccine. Dr. Morgan noted a "completely normal neurological exam" that day apart from some chorea in her fingers, a slight tremor, and hyperflexible joints. *Id*. Dr. Morgan wrote this is a "[c]omplex story here with behavioral and psychiatric components" and an exam not typical of chorea, encephalitis, or encephalopathy. *Id*. at 29. He wrote that varicella meningoencephalitis can occur in patients, but petitioner's MRI is normal and "she never had devastating disease." *Id*. Dr. Morgan was more worried about petitioner's behavioral components than an autoimmune encephalopathy. *Id*.

[28] Petitioner received an MMR vaccine at age 5—not a varicella. Her first varicella vaccine was at age 11. Pet. Ex. 15 at 3.

Petitioner and her mother presented to Dr. McKean on March 3, 2016 for asthma. She was 18 years old. The history provided included seeing a neurologist at Georgia Regents University in October and being found to have abdominal reflux, cerebellar damage,[29] and ataxia.[30] Pet. Ex. 4 at 1. A lumbar puncture in December of 2015 showed 7 WBCs and elevated albumin with no evidence of autoimmune encephalitis. She was not diagnosed with myasthenia gravis. A MoCA test showed dementia.[31] She was still working and had not been ill but complained of fatigue. *Id*. Dr. McKean's impression was mild, intermittent asthma and selective IgA and IgM immunodeficiency.[32] *Id*. at 2. She received a pneumovax vaccine on that day. *Id.*

Petitioner and her mother returned to Dr. McKean on March 24, 2016 reporting increased neurological symptoms following the pneumovax vaccine with staring episodes, irritability, and being confrontational but overall the changes were not severe. Pet. Ex. 4 at 3. Examination was normal/negative. *Id*. at 3-4.

Petitioner was returned to Dr. Morgan on March 16, 2016 for a neuropsychological evaluation. The history provided included two episodes of behavior changes after MMR and varicella vaccines at ages 5 and 16, both times with a decline in school achievement. Pet. Ex. 12 at 10. She was reportedly diagnosed with "putative complex partial seizures in early 2014 and started on Lamictal." *Id*. She had an extensive workup at Emory during the summer of 2015 for autoimmune encephalitis. Incidental labs suggested myasthenia gravis although she had no symptoms. *Id*. Cognitive complaints included forgetfulness, poor concentration, word finding difficulties, and blank thoughts. She reported auditory hallucinations a year ago on more than one occasion. *Id*. Petitioner had undergone several psychological evaluations with "highly variable results". *Id*. Dr. Morgan's impression was deficits in attention and concentration and reduced mental processing speed but an otherwise unremarkable cognitive examination. *Id*. at 11. Intellectual function was average to low average while reading was borderline, and she had mild symptoms of depression. *Id*. The pattern of cognitive deficits was "nonspecific with regard to etiology", inconsistent with limbic (anti-NMDA receptor) encephalitis, but most commonly seen in patients with significant psychiatric disorders. *Id*. at 12. There were multiple symptoms of significant personality disorder with many borderline traits on prior testing. The diagnostic impression that day was unspecified mild neurocognitive disorder. *Id*.

Petitioner and her mother returned to Dr. Morgan on April 12, 2016. Pet. Ex. 12 at 1, 4. The mother reported that petitioner had memory decline, behavioral issues, and chorea. *Id*. at 4. She further reported that during a repeat EEG, petitioner had hand shaking, oscillating eyes and

[29] The cerebellum is the part of the brain that occupies the posterior cranial fossa posterior to the brainstem and is concerned in the coordination of movements. *Dorland's* 327.

[30] Ataxia refers to failure of muscular coordination or irregularity of muscular action. *Dorland's* 168.

[31] The MoCA test is used to interpret the level of cognitive impairment based on a score out of 30 possible points. A score of 26 and above is considered "normal." Shilpa Amin, M.D., CAQ, FAAFP, *What is the MoCA Test for Dementia?*, MedicalNewsToday, https://www.medicalnewstoday.com/articles/moca-test-for-dementia#what-to-expect. *Petitioner received a score of 27.* Pet. Ex. 12 at 65. (emphasis added)

[32] IgA deficiency is the most common immunodeficiency disorder: deficiency of IgA with normal levels of the other immunoglobulin classes and normal cellular immunity. It is marked by recurrent sinopulmonary infections and an increased incidence of allergy, gastrointestinal disease, and autoimmune diseases. Many patients have anti-IgA antibodies that can cause severe transfusion reactions. *Dorland's* 472, 908-09.

uncontrolled blinking, Tourette-like symptoms, facial twitching, and significantly decreased IQ. *Id*. Petitioner had seen an immunologist every three months since the summer of 2015 and was found to have no immunity to varicella zoster and "activated" HHV6. *Id*. at 5. Tests showed low IgA and IgM but normal IgG levels. She reported that Dr. McKean diagnosed petitioner as immunocompromised and thought "her 'encephalitis' picture might be from HHV6 reactivation from VZV vaccine". The mother called the CDC and was told not to give petitioner any live attenuated vaccines in the future. *Id*. Petitioner required special school accommodations after the varicella vaccine and was later admitted to Athens Tech College for low remedial scores in all subjects, but this was postponed until later. Petitioner works part-time at a special education preschool and resides in a basement apartment at her parents' house. The mother reported similar behavior issues at age 5 following MMR vaccine. *Id*. Dr. Morgan's impression remained fine tremor in her hands not likely chorea, with an otherwise normal examination. *Id*. at 5-8.

Genetic testing performed on May 31, 2017 showed a normal female. Pet. Ex. 36 at 1, 3.

There was a gap in the medical records from May 2017 until February 2019, at which time petitioner was pregnant. Her pregnancy was complicated by shortness of breath, psychiatric illness, myasthenia gravis, "nervous system disease," obesity, and other mental disorders. Pet. Ex. 45.1[33] at 4.

Petitioner and her mother presented to Dr. McKean on February 26, 2019 for difficulty breathing over the past two months. The mother reported that petitioner had myasthenia gravis, felt weak in the morning, and had difficulty with tremors in the past. Pet. Ex. 39 at 2. Dr. McKean's impression was moderate persistent asthma and immunodeficiency. *Id*. at 3. Dr. McKean discussed at length with petitioner and the mother that petitioner's baby may also have immune deficiencies. *Id*.

Petitioner presented to Dr. Rivner on February 27, 2019. She was last seen in 2015. She reportedly had psychiatric problems, muscle weakness, shortness of breath, and fatigue, and she was pregnant. Pet. Ex. 38 at 1. She reported having encephalitis in the past and choreoathetosis. She had no seizures but was on medication. Her IQ was improving, but she still had foggy memory. *Id*. Examination that day was normal. *Id*. at 2. Dr. Rivner concluded that while it was possible she had myasthenia gravis, she had atypical symptoms and IVIG was not a good treatment option for her because she has IgA deficiency. *Id*. at 3.

Petitioner then presented to Dr. Lacayo on March 6, 2019 to discuss treatment for myasthenia gravis in light of immune deficiency. PLEX was to be used in a crisis. IV steroids could be used for acute weakness. It was reported that Dr. Rivner had recently conducted extensive testing for myasthenia gravis, and the results were pending. Pet. Ex. 40 at 8.

Petitioner returned to Dr. McKean on March 26, 2019 doing better with medication but with continued dyspnea at rest "likely due to a combination of pregnancy and myasthenia gravis." Pet. Ex. 39 at 7.

[33] Petitioner filed two exhibits numbered 45 into the record. Thus, for ease of citation, "Pet. Ex. 45" refers to the filing located at ECF No. 78, and "Pet. Ex. 45.1" refers to the filing located at ECF No. 79.

Petitioner and her mother returned to Dr. Rivner on March 27, 2019. He diagnosed her with myasthenia gravis due to abnormal test results, even though she presented with "very atypical" symptoms. Pet. Ex. 38 at 5, 7. He noted that she was a high risk delivery with a chance of neonatal myasthenia gravis in the child. *Id*. at 7.

The mother called Dr. Lacayo's office on April 2, 2019 to advise that petitioner was scheduled to deliver her baby on April 10, 2019 by C-section, her immune labs were "bad", and her myasthenia gravis progressing. She reported positive neurofiber EMG testing with Dr. Rivner and that IVIG was needed. Pet. Ex. 40 at 3; *but see* Pet. Ex. 38 at 3, where Dr. Rivner specifically advised against the use of IVIG in petitioner. Petitioner was being admitted that day for a 3-day course of IVIG. Pet. Ex. 40 at 3. Petitioner asked that Dr. Lacayo prescribe petitioner's medications because she had missed her last psychiatrist appointment, and the psychiatrist would not prescribe the medication. *Id*.

Petitioner was admitted to Piedmont Healthcare on April 2, 2019 to receive IVIG prior to delivery of her baby in order to reduce respiratory complications, risk of MG in the baby, and post-delivery complications. Pet. Ex. 45.1 at 5, 9. Upon admission, the mother reported that petitioner suffered an "immune mediated neuro injury after getting a vaccine booster for chicken pox at age 16 and has subsequently been diagnosed with autoimmune encephalitis, myasthenia gravis, immunodeficiency including IgA deficiency and epilepsy." *Id*. at 11.

Petitioner suffered from headache, chest pain, back pain, parasthesias, and tingling from IVIG treatment, all of which are adverse reactions. The IVIG rate was slowed, and she was able to finish treatment but had recurrent symptoms after discharge, requiring IV steroids and fluids. Pet. Ex. 45.1 at 38, 41.

Petitioner's baby was born on April 10, 2019. Pet. Ex. 45.1 at 72, 75. She continued to complain of shortness of breath so pulmonary work up was conducted. *Id*. at 58-62. Chest x-ray and CT angiogram ruled out pulmonary embolism and pneumonia. *Id*. at 65. Her shortness of breath was believed to be multifactorial due to myasthenia gravis, asthma, and anemia. *Id*.

The mother called Dr. Lacayo on May 16, 2019 requesting that he write a letter stating that petitioner is stable enough to take care of her baby and work in law enforcement. Pet. Ex. 40 at 5-6. That letter, if written, was not filed.

Petitioner returned to Dr. Rivner on May 29, 2019 with complaints of fatigue and generalized body weakness. Pet. Ex. 38 at 9. Dr. Rivner's impression was asymptomatic myasthenia gravis, side effects from IVIG and obstructive, not restrictive, airway disease. *Id*. at 11.

At her June 7, 2019 visit with Dr. Lacayo, her serology was reportedly positive for myasthenia gravis and immune disorder. She had suffered from "chemical meningitis" as a reaction to IVIG treatment. Pet. Ex. 40 at 1, 3. She complained of shortness of breath, fatigue, dizziness, tremors, and numbness. *Id*. at 3. The baby was doing well. *Id*. Dr. Lacayo's assessment was myasthenia gravis, unremarkable tremor, and common variable immunodeficiencies. *Id*. at 4-5.

B. Affidavits

i. Petitioner's Affidavit

Petitioner filed an affidavit on July 7, 2016. Pet. Ex. 1. She stated she was generally healthy at the time she received the varicella vaccination on July 2, 2013. *Id*. at 1. During that visit, she reported wiggling in her fingers that she planned to see a neurologist for but confirmed no significant medical history. *Id*. at 1-2.

Petitioner affirmed that she presented to the ER on July 5, 2013 complaining of an allergic reaction to the vaccination with difficulty breathing and swallowing. Pet. Ex. 1 at 2. A rapid strep test was positive, but a throat culture that was performed at her mother's "insistence" was negative. She was given steroid and antibiotic injections and sent home. *Id*.

Petitioner affirmed that she presented to Dr. McKean on July 16, 2013 for allergies and asthma. Pet. Ex. 1 at 2. Dr. McKean noted her difficulty breathing and enlarged uvula after the vaccination. *Id*. Two days later, she presented to Dr. Lacayo for her "new onset tremors." Dr. Lacayo diagnosed her with "essential and other specified forms of tremor and unspecified diffuse connective tissue disease." *Id*. at 2-3.

Following an assessment by Dr. Dyer on July 24 and 26, 2013, petitioner was diagnosed with a reading and anxiety disorder. Pet. Ex. 1 at 3. Beginning in August 2013, she had "severe emotional outbursts, anger issues, staring spells, and overall worsening behavioral issues that [she] seemed unable to control." She affirmed these problems worsened throughout the fall and winter of 2013, eventually culminating in a "psychotic breakdown" in January 2014. *Id*.

Petitioner affirmed that an EEG performed in January 2014 was suggestive of a seizure disorder and cerebral dysfunction. Pet. Ex. 1 at 3. Her neurologist then ordered an MRI and concluded "she has a seizure disorder causing her behavior disorder including belligerence, agitation and impaired insight." *Id*. Petitioner started taking Lamictal. *Id*. at 4.

Petitioner affirmed that she presented to Dr. Lacayo on March 3, 2014, but he was unsure of the "cause and effect relationship" between her symptoms and the vaccination, but "the timing does suggest a correlation" and it seemed that the vaccination "aggravated her condition." Pet. Ex. 1 at 4.

According to petitioner, she had another abnormal EEG on March 24, 2014. Pet. Ex. 1 at 4. She was placed in inpatient care between April 5 and 9, 2014 for continued erratic behavior and angry outbursts, and was assessed as having a mood and seizure disorder. She affirmed her physician during inpatient treatment found that her anger was due to central nervous system dysfunction. *Id*.

Petitioner affirmed going to Eastern Atlanta Behavioral Health where she was noted to have episodes of obsessive thinking, seizures, erratic behavior, suicidal ideations, and severe mood swings due to multiple possible etiologies, including seizures. Pet. Ex. 1 at 4-5.

According to petitioner, she presented to Emory for evaluation of seizures and staring spells over the last 6-12 months, with psychiatric symptoms which presented around the same time. She was diagnosed with new onset partial seizures. Pet. Ex. 1 at 5.

Petitioner affirmed that in August of 2014, her psychologist noted a decline in her behavioral and emotional functioning over the past year. Pet. Ex. 1 at 5. The psychologist wrote "there is evidence to suggest a causative link between vaccinations and periods of cognitive decline and diagnosed [her] with a Major Neurocognitive Disorder." *Id*.

According to petitioner, her symptoms persisted over the next year, although some were controlled by medication. Pet. Ex. 1 at 5. She was seen again at Emory in August 2015 and diagnosed with a seizure disorder. *Id*. at 6. She was also referred for a neuroimmunology evaluation because her symptoms may be related to the vaccination. *Id*.

Petitioner affirmed she was determined to be immunodeficient and her neurologist opined that her symptoms in the context of her immunodeficiency were more likely than not caused by the varicella vaccine. Pet. Ex. 1 at 6. Her immunologist's opinion is also that she had a severe adverse reaction to the varicella vaccine and should not have any live-virus vaccines in the future. *Id*.

ii. The Mother's Affidavit

The mother affirmed that petitioner received her first MMR vaccine at 22 months. Pet. Ex. 35 at 1. Petitioner then had "negative behavioral changes", but the parents attributed it to "a case of the 'terrible twos.'" *Id*. at 2.

The mother affirmed that petitioner received a second MMR vaccine at age 5 in June 2002. Pet. Ex. 35 at 1-2. After that vaccination, petitioner developed new cognitive and behavioral issues that were not typical for a child her age, such as illogical behavior, inappropriate risk taking, extreme disobedience, insomnia, screaming fits, attention issues, cognitive decline, and muscle and coordination issues. She was referred for an occupational therapy evaluation as a result. *Id*. at 2.

According to the mother, in June 2003 when petitioner was 6 years old, she was taken for psychological evaluation with Dr. Cates. Dr. Cates prepared a neurodevelopmental therapy curriculum for use in homeschooling petitioner. Pet. Ex. 35 at 2-3. Dr. Cates retested petitioner in June 2004 and she showed improvement, so he provided another customized curriculum to use at a school he recommended, Basic Trust Child Development Center. *Id*. at 3. Dr. Cates also sent petitioner for comprehensive audiologic assessment and auditory processing testing in August 2004 and for a vision therapy assessment in October 2004. *Id*. Petitioner had an OT evaluation in February 2005. *Id*. at 3-4. Dr. Cates evaluated petitioner a third time in June 2005 and prepared a curriculum to be used at Churchill Academy, a grade school run by the owners of Basic Trust Child Development Center. Petitioner went there for the first half of the school year. *Id*. at 4. They then moved to Alabama, and she attended Huntsville Christian Academy. *Id*.

According to the mother petitioner was homeschooled in 2008, due to the cost of private school. In 2009, she was enrolled in The Ellis Academy for Girls where she went until 2011. She excelled in the arts and was "acting like a normal child." While in Alabama, petitioner was treated at Millstone Pediatrics but had an aversion to male doctors. Pet. Ex. 35 at 4.

The mother affirmed that due to her own personal health issues, the family moved to Georgia in 2011 to be closer to family. Petitioner was homeschooled during the 2011-2012 academic year. Pet. Ex. 35 at 4-5. In 2012, all of their children were enrolled in Trinity Prep School. Petitioner did not enjoy that school, so she finished her sophomore year of high school at Faith Academy, where she did well academically. *Id*. at 5.

The mother affirmed that for petitioner to attend public school for the 2013-2014 academic year, she had to be up to date on her vaccinations. She was taken to Groff to establish a new pediatric relationship on July 2, 2013 and was given the varicella vaccine. She was taken to the ER "[o]nly days later…with a reaction to the vaccine." Pet. Ex. 35 at 5.

According to the mother, petitioner had no significant medical appointments between May 10, 2010 and July 2, 2013. Since she had no serious health issues and an aversion to doctors, she did not see any doctors during that time. Pet. Ex. 35 at 5-6.

C. Other Documentation and Evidence

i. Letter from Dr. Cates

Dr. Cates "worked with [petitioner] and her parents in a strictly academic capacity" through Faith Christian Ministries. Pet. Ex. 26 at 1. According to his CV, Dr. Cates is the President and Founder of Faith Christian Ministries where he provides Individual Cognitive Plans ("ICPs") for each student. *Id*. at 4. He has a Ph.D. in curriculum and instruction from Loyola University. *Id*.

Dr. Cates appears to have responded to a letter requesting him to provide information about petitioner. In a letter dated September 30, 2016, he wrote about petitioner's time as a student at Faith Christian Ministries in 2003, 2004, and 2005 and the ICPs created for her based on testing. Pet. Ex. 26 at 1. The family contacted Dr. Cates when they noted "extreme behavioral changes" in petitioner at 5 and 6 years old. Testing showed signs of autism spectrum disorder. An educational program was developed, and she was successful in her academic performance throughout 2003. *Id*.

After further testing in 2004, Dr. Cates suggested she see Dr. Hall at the University of Florida. Pet. Ex. 26 at 2. Following testing by Dr. Hall, petitioner was diagnosed with hyperacusis.[34] He recommended OT and formal and comprehensive assessment of phonologic awareness and reading comprehension by a speech pathologist. Petitioner had a "serious deficit in maintaining attention during auditory tasks." *Id*. Basic Trust Kindergarten in Kentucky was recommended, and she was enrolled. She excelled in school in 2004. *Id*.

[34] Hyperacusis is exceptionally acute hearing wherein the hearing threshold is unusually low. *Dorland's* 875.

Petitioner was tested again by Dr. Cates in 2005, and a new educational plan was created to be used at Churchill Academy. Pet. Ex. 26 at 2. He has not had regular contact with the family since they pursued other educational options for petitioner. *Id*. at 3.

ii. School Records

Throughout her education, petitioner was homeschooled and attended various schools in different states. Petitioner's learning disabilities were evident early on and accommodations were made to assist in her education.

Her records from Huntsville Christian Academy for 2005 showed that petitioner did well despite "hardships on the rest of the family [that] were profound." Pet. Ex. 20 at 11. Her records for third and fourth grades (2005/2006 and 2006/2007) showed her to be an A student. *Id*. at 1. She was withdrawn from Huntsville Christian Academy on January 22, 2007, and then homeschooled. *Id*.; Pet. Ex. 23 at 6. She also attended Hope and A Future, Inc. during this timeframe. *See* Pet. Ex. 22.

Petitioner attended The Ellis Academy from 2009-2011, where she was an average C+ student who excelled in the arts. Pet. Ex. 23 at 1, 3.

Petitioner attended Trinity Prep School from August 2012 through January 2013. Pet. Ex. 21 at 4, 13; Pet. Ex. 24. She took choir and dramatic arts at Master's Academy of Visual & Performing Arts and attended courses at Walton Youth Chorale. Pet. Ex. 21 at 5-8, 12.

Petitioner attended Strong Wall Academy in 2013-2014. *Id*. at 9; Pet. Ex. 25. The parent questionnaire form includes that petitioner had "centralized auditory processing [and] visual processing delays". Pet. Ex. 25 at 4.

In addition to petitioner's regular schooling, she also attended Faith Christian Academy, which offers college-prep courses, from 2011-2014. Pet. Ex. 21 at 1.

iii. Pro Se Report

On December 5, 2019, petitioner submitted a 59-page document titled, "Pro Se Report - Prong 1, 2 & 3 combined". Pro Se Report, ECF No. 56-1. This document is authored by the mother. She submits that Dr. McKean and Dr. Lacayo

> . . . already expressed their confidence that it was more likely than not that the vaccine and it's (sic) components were the trigger that set off the catalyst of life altering medical declines, but, the court felt that their documents, even coupled with the vast amount of labs, and testing results that support their claims, were not sufficient and that more expert witnesses were needed or those specialists needed themselves to document how the Petitioner's particular injury was caused or triggered by the vaccine via the aforementioned mechanisms, including requirements noted in Prong 3 that requires an expert to explain how the timing of

the onset of the Petitioners (sic) injuries supports a finding that the vaccine caused the injury. *Id*. at 2.

In short, the mother argued that petitioner received a live vaccine contraindicated because she is immunocompromised. The live vaccine triggered a "catalyst of Neuroimmune mediated responses throughout her body and mind, that have permanently altered her life." Pro Se Report at 54.

Much of the content of the Pro Se Report is repeated in the mother's "Expert Opinion" and petitioner's response to the Motion to Dismiss, both of which are detailed below.

D. Expert Reports

i. Petitioner's Experts/Treating Physicians

a. Letter from Dr. Juan Lacayo

Dr. Lacayo wrote two opinion letters. Pet. Ex. 10; Pet. Ex. 41.

In his first letter dated April 26, 2016, Dr. Lacayo wrote that petitioner presented to him on July 18, 2013 with "dance-like tremors." The only triggering mechanism identified was a vaccine prior to the symptoms. Pet. Ex. 10 at 1. PANDAS and Wilson's were excluded. Petitioner's condition then deteriorated with poor school performance and behavioral changes. An EEG showed lateralized abnormality with epileptiform discharges. *Id*. She was prescribed Lamictal from January to June of 2014 to stop epileptiform discharges from producing subclinical seizures. She was evaluated by psychiatry as both an inpatient and outpatient. She could not maintain enrollment in school. She was evaluated at Emory and had an improved EEG "when seizure medication was increased to FDA-approved maximum dosage." She continues to require treatment for neuro-psychiatric disorders including but not limited to alteration in awareness and unspecified tremors. She has recently been diagnosed with immune deficiencies which explains why her neurological system responded adversely to live vaccines. *Id*.

Dr. Lacayo concluded that petitioner's symptoms are due to the effects of the vaccine. He recommended she have access to the vaccine compensation program because "the vaccine in [his] medical opinion can be the causation of her symptomology." Pet. Ex. 10 at 1.

In a second "Opinion Letter" dated January 25, 2021, Dr. Lacayo wrote that petitioner presented on July 18, 2013 "with tremor" and "abnormal movements" and her "behavior dramatically worsened during that time." Pet. Ex. 41 at 1. An EEG performed in January 2014 showed "abnormal epileptiform activity", but an MRI was normal. Seizure medication was started based on the EEG results and reports of movements. *Id*.

Dr. Lacayo wrote that, in 2014, the mother advised him that petitioner's tremor began in July 2013—not earlier. Pet. Ex. 41 at 1. She advised him that petitioner received a varicella booster on July 2, 2013 and presented to the ER within 72 hours with "uvula edema [and] respiratory

distress" requiring steroid injection. "It was after that time the tremor-like movements appeared." Work up for Wilson's Disease and PANDAS were normal. *Id*.

Dr. Lacayo stated that after her ER visit, petitioner developed behavioral decline, severe psychiatric problems, and cognitive decline, which he claimed was "evident by full scale IQ change from 102 in July 2013 to 79 in August 2014". Pet. Ex. 41 at 1. Medication showed some clinical improvement. "It took 6 months for EEG to normalize…suspicion for encephalitis was significant given the marked changes in a short period." *Id*. She was "referred to Emory Epilepsy Center" for continuing behavior problems and episodes of "'spacing out'". *Id*. Emory's test results revealed epileptiform activity on EEG which had improved, but her behavior did not. *Id*.

According to Dr. Lacayo, throughout this time, petitioner took medications for "presumed allergies", and she was evaluated by Dr. Rivner for continued symptoms, and he diagnosed her with myasthenia gravis. Pet. Ex. 41 at 1. A lumbar puncture showed "elevated WBCs and albumin, confirming encephalitis, which is a condition in which the brain has diffuse inflammation causing impairment in function as well as changes in behavior like agitation, behavior disturbances and psychiatric disorders." *Id*. at 1-2. Further, she was diagnosed with primary immunodeficiency by Dr. McKean in 2015. *Id*. at 2. She had a difficult pregnancy due to myasthenia gravis, and the baby had myasthenia gravis syndrome after delivery. Petitioner required IVIG due to her "MG crisis" of profound weakness and decline in respiratory function. *Id*.

Dr. Lacayo added that with further history taking between himself and the mother, he concluded that petitioner suffered a similar decline at age 5 following an MMR vaccine. Pet. Ex. 41 at 2. "Retrospectively, this may have been a similar, but milder, incident involving her immune system which was evaluated but not diagnosed." *Id*. Further research into her history was needed to understand the changes that followed vaccinations. *Id*.

According to Dr. Lacayo, "immune-logically (sic) abnormal patients may experience more adverse effects and are at a higher risk of adverse effects" from live attenuated vaccines like varicella. Pet. Ex. 41 at 2. The package insert for varicella vaccine is associated with adverse effects such as encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barre syndrome, Bell's palsy, ataxia, non-febrile seizures, aseptic meningitis, meningitis, dizziness, and paresthesia. He claimed that the package insert also states that "[c]ases of encephalitis or meningitis caused by vaccine strain varicella virus have been reported in immunocompetent individuals previously vaccinated with VARIVAX months to years after vaccination." *Id*. The package insert was not filed into the record in this case.

Dr. Lacayo concluded that petitioner's immune status was unknown when she received her vaccines and "her neurological symptoms are a direct result from immune-mediated adverse effects from vaccination; abnormal movements, abrupt behavior changes and epilepsy from encephalitis, myasthenia gravis from abnormal immune system activation." Pet. Ex. 41 at 2. Dr. Lacayo added that petitioner's diagnoses have accumulated since 2013 and include: anaphylactic allergic reaction within 2-72 hours following vaccine; movement disorder with Chorea-Athetoid Movements; Complex Partial Seizures with epileptiform discharges on EEG; neurocognitive and IQ decline; exacerbation/aggravation of primary immune deficiency; immune related cerebral injury; encephalitis; myasthenia gravis with acetycholine-receptor antibodies; major depressive

disorder; and psychosis. *Id*. at 2-3. He claimed "[s]he has permanent life plan alteration as a result of the above diagnoses." *Id*. at 3.

b. Letter from Dr. Lawrence McKean

On May 13, 2016, Dr. McKean wrote a letter stating that petitioner has primary immune deficiency, specifically IgA, IgM, and Mannose Binding Lectin[35] Deficiency. Pet. Ex. 11 at 1. She suffered an "adverse reaction to the Varicella Zoster (Shingles) vaccine" in July 2013. She then had a decline in cognitive function and other neurological symptoms. "The fact that she was unable to mount an immune response to the Varicella Zoster vaccine (negative IgG and IgM antibody to varicella documented in 08/2015) provides further evidence that her immune deficiency is clinically relevant. Indeed, it is an indication that she is at risk from any live virus vaccine." *Id*. (emphasis in original). Her immune deficiency was not known at the time she received the vaccine. He concluded that petitioner "has had a severe adverse reaction from the Varicella Zoster vaccine." *Id*.

c. The Mother's "Expert Opinion"

On March 2, 2021, the mother filed a document titled, "Various Medical Experts Combined with Medical Theory, Logical Sequence with Temporal Relationship with Vaccine to Injury". Pet. Ex. 54. This 35-page document includes several embedded hyperlinks[36] to various sources to satisfy the requirements set forth in *Althen*.

According to the mother, petitioner was unable to secure an attorney or an expert witness "because of the wording of the Rule 4c, and the Petionn (sic) for Compensation." Pet. Ex. 54 at 2. Therefore, she cited that "[t]he leading experts on Vaccines are the CDC, ACIP and the Varicella Vaccine Manufacturers", who "testif[ied] in their own documentation of their medical theories which more than causally connect the Varicella vaccine specifically to being INJURIOUS to those who have Primary Immune Deficiency." *Id*. at 1 (emphasis in original).

The mother submits that petitioner has Primary Immune Deficiency. The CDC "contraindicates the administration of LIVE VACCINES (including MMR & Varicella) to Primary/Congenital Immune Deficiencies children" and warns that the chicken pox vaccine is contraindicated in those with a weakened immune system and history of immune system problems. Pet. Ex. 54 at 2-3.[37] Additionally, the Pink Book provides that the most frequent complications with varicella vaccine in immunocompromised individuals are pneumonia and encephalitis, which

[35] Mannose Binding Lectin is a protein that is structurally similar to complement component C1 and recognizes many microorganisms, including bacteria, fungi, parasites, and viruses. It initiates the lectin pathway of complement activation, without the presence of antibody, by binding to carbohydrates on the microbial surface and activating C3. *Dorland's* 1003.

[36] The various sources the mother cited to in this brief were embedded in the document but not filed into the record.

[37] To support this statement, the mother cited to the following: Centers for Disease Control and Prevention, *Contraindications and Precautions*, https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html; Centers for Disease Control and Prevention, *Chickenpox (Varicella) Vaccines*, https://www.cdc.gov/vaccinesafety/vaccines/varicella-vaccine.html#:~:text=CDC%20recommends%20two%20doses%20of,age%204%20to%206%20years.

is what happened to petitioner. *Id*. at 3.[38] She further listed all the post-marketing adverse events contained in the varicella vaccine insert. *Id*. at 4.[39]

The mother argued that children are not tested for "Innate Immune system competency" prior to being administered live vaccinations. Petitioner's immunodeficiency was not discovered "until the damage had already been done." Pet. Ex. 54 at 4, 6. The mother claimed that petitioner suffered many childhood illnesses but did not get an immune blood workup as a child, so she received vaccines that were contraindicated for her, including the subject varicella vaccine at age sixteen. *Id*. at 4-6; *see also* Pet. Ex. 52.

The mother submitted that petitioner obtained several diagnoses, "all of which were new onset, following the July 2, 2013 Varicella Vaccine." Pet. Ex. 54 at 5; *see also* Pet. Ex. 41 at 2-3.

The mother further claimed that Dr. Helmers, the Chief of Epilepsy at Emory, diagnosed petitioner with "a Neuro-Immune mediated brain injury", but informed the parents that there was no one qualified at Emory or in the state of Georgia to treat petitioner. Thus, Dr. Helmers suggested petitioner go to the University of Pennsylvania. Pet. Ex. 54 at 6.

The mother submits that petitioner was seen by Dr. Rivner, a leading specialist in myasthenia gravis, who performed a lumbar puncture and sent her spinal fluid to the University of Pennsylvania for testing. Pet. Ex. 54 at 6-7. Dr. Rivner diagnosed petitioner with myasthenia gravis.

The mother further submits that Dr. McKean cautioned petitioner not to receive any more live vaccines because "he was confident that Vaccine had done the damage." Pet. Ex. 54 at 7; *see also* Pet Ex. 11. The mother conceded that Dr. McKean's letter did not provide a "mechanism by which the vaccine does in fact harm primary immune deficiency patients" but stated that is because it appears that no one knows the mechanism. Pet. Ex. 54 at 7.

The mother then proposed several medical theories in this case to satisfy *Althen*.

1. Medical Theory #1

The mother's first theory was based on the contraindications for administering varicella vaccine to those who are immunocompromised or have a family history of immunocompetence. Pet. Ex. 54 at 9-10.[40] For Prong I, she argued that in immunocompromised individuals, live vaccines may cause severe systemic disease and are documented as unsafe by the National Institute of Health. *Id*. at 10, 21. She argued that petitioner has congenital B-cell immunodeficiency, combined variable immunodeficiency, and quantitative immunoglobulin levels based on blood work ordered by Dr. McKean and Dr. Rivner. *Id*. at 10-11.[41]

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[38] To support this statement, the mother cited to the following: Adriana Lopez, MHS, et al., *Varicella*, *in* EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 329, 332 (14th ed. 2021).

[39] The mother cited to the following: U.S. Food & Drug Administration, *Package Insert – Varivax – Frozen Storage*, https://www.fda.gov/media/119865.

[40] *Supra,* note 37.

[41] The mother did not cite to petitioner's medical records. Petitioner's records show that she had mildly low levels of IgA and IgM, normal IgG, and low Mannose-Binding Lectin. Pet. Ex. 39 at 7, 10.

For Prong II, she argued that upon receipt of the varicella vaccine on July 2, 2013, petitioner suffered a "systemic inflammatory response" initially presenting as airway restriction requiring the use of Albuterol via nebulizer "at 24 hours post vaccine, continuing for the next week".[42] Pet. Ex. 54 at 11. At 72 hours post-vaccination, petitioner had difficulty breathing, airway restriction, and an enlarged uvula, prompting an ER visit. The ER doctor administered Solu-Medrol for an allergic response. Neurological signs manifested that same week with a tremor that had never been identified prior on the record; in the alternative, if the tremor was present prior to vaccination, it was "severely aggravated". *Id*. Petitioner developed other neurological signs of inflammation, including "mood alterations, personality changes, agitation, irritability, mood lability, aggressiveness, impaired insight", which were "early indicators of CNS involvement and likely early encephalitis, indicating the Blood brain barrier had likely failed to protect the CNS from invasion due to the immunodeficient status of [petitioner]." *Id*. at 11-12. Progressive signs of CNS inflammation continued with decline in IQ and academic performance, which suggested encephalitis. *Id*. at 12. Brief stares and alteration of consciousness led to EEG testing, which showed evidence of a systemic attack on the brain either from the live virus or its components causing epileptiform discharges and cerebral dysfunction in the left hemisphere. *Id*. She developed psychiatric issues and "[t]he formation of Autoimmunity by the appearance of AChR antibodies manifesting as NEW ONSET Myasthenia Gravis." *Id*. (emphasis in original). She also had episodes of rashes, hives, urticaria, itching, and paresthesia. *Id*.

For Prong III, the mother argued that the "onset of complications in the form of allergic reaction definitely correlates with the introduction of the contraindicated live vaccine on July 2, 2013, into the host and all diagnosis (sic) that follow." Pet. Ex. 54 at 13. She had a severe aggravation of a mild movement disorder which evolved into "worrisome chorea athetoid movement disorder". *Id*. Petitioner was diagnosed with several conditions after the "contraindicated vaccination", including epilepsy, seizure disorder, complex partial seizures, nystagmus, ataxia, cerebral dysfunction, all psychiatric symptoms, myasthenia gravis, major neurocognitive disorder/dementia, encephalopathy, encephalitis, major depressive disorder, immune mediated brain injury, HHV6 reactivation, and personality disorder. *Id*.

2. Medical Theory #2

For her second medical theory, the mother argued that the varicella virus has been documented as an etiology for myasthenia gravis via molecular mimicry. Thus, the vaccine could cause a person to make auto antibodies to AChR via molecular mimicry, as well. Pet. Ex. 54 at 14. The mother cited to an abstract of a case report[43] of a five-year-old presenting with oculobulbar weakness two weeks after varicella zoster infection and a four-year-old who developed facial diplegia and dysarthria several weeks after viral pharyngitis. *Id*. Molecular mimicry between AChR and viral proteins was considered a possible immune response to the variant of myasthenia gravis. *Id*.

[42] Petitioner's use of Albuterol one day after the vaccine is not documented in the medical records.

[43] The mother cited to the following: Kevin J. Felice et al., *Postinfectious Myasthenia Gravis: Report of Two Children*, 20 J. OF CHILD NEUROLOGY 441 (2005).

For "MECHANISM 2", the mother submitted that petitioner developed antibodies "as a result of residual DNA ingredients in varicella vaccination that are human and cross reactive, which resulted in neuropsychiatric manifestations, including epilepsy, and connective tissue disorder and movement disorders." Pet. Ex. 54 at 15. As "Proof", she stated that the "varicella vaccine (Varivax) contains ingredients, proteins and DNA that are human derived and can cause autoimmunity, specifically, the MRC-5 cells, which the FDA acknowledges contains 'small amounts of residual cell substrate DNA in all viral vaccines.'" *Id.*[44] Citing Wikipedia, she listed the ingredients of the varicella vaccine and stated that MRC-5 is a human diploid cell culture line composed of fibroblasts from fetal lung tissue, with fibroblasts as the most common cell of connective tissue in animals. *Id*. Further, the mother argued that an FDA Briefing Document[45] states that small amounts of residual cell substrate DNA occur in all viral vaccines and can be oncogenic or infectious. *Id*.

3. Medical Theory #3

The third medical theory also involves petitioner being immunocompromised prior to her being vaccinated with live vaccines and the lack of testing for "Immunocompetence" prior to administering live vaccines to children. Pet. Ex. 54 at 16. She submits that the information given to parents prior to vaccinations is inadequate. *Id*.

According to the mother, petitioner's "fate [was] already known by all Vaccine authorities" in that her immunodeficiency "would be immediately aggravated by an antibody Mediated Autoimmune Response." Pet. Ex. 54 at 16, 21 (emphasis in original). Citing an article[46] involving anaphylaxis, the mother argued that petitioner's initial "Insult" involved a "BiPhasic Anaphylactic Reaction", which included an asthma attack within an hour of receiving the varicella vaccine. *Id*. at 16-17. She described the mechanism involved in an asthma attack and how an allergic response occurs when antibodies mistakenly identify a harmless substance as an invader, like the antigen or components of the live vaccine, and attempts to protect the body by binding to the allergen. *Id*. at 18.[47] She claimed that there are a few treatments that are designed to treat both asthma and allergies, such as a leukotriene modifier. *Id*. at 22.[48]

The mother stated that the cause of autoimmunity is not known but is theorized to be due to environmental factors, like bacteria or viruses, that trigger "changes that confuse the immune system." Pet. Ex. 54 at 22.[49] In genetically susceptible people, environmental triggers may induce

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[44] It is not clear where this quote comes from.

[45] FDA Briefing Document, *Vaccines and Related Biological Products Advisory Committee Meeting: Cell Lines Derived from Human Tumors for Vaccine Manufacture*, https://wayback.archive-it.org/7993/20170113080336/http:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM319573.pdf.

[46] James J. Arnold, D.O. & Pamela M. Williams, Col., Lt., USAF, MC, *Anaphylaxis: Recognition and Management*, 84 AM. FAMILY PHYSICIAN 1111 (2011).

[47] The mother cited to the following to support this statement: James T.C. Li, M.D., Ph.D., *Allergies and Asthma: They Often Occur Together*, https://www.mayoclinic.org/diseases-conditions/asthma/in-depth/allergies-and-asthma/art-20047458.

[48] *Id*.

[49] The mother cited to the following to support this statement: National Library of Medicine: MedlinePlus, *Autoimmune Disorders*, https://medlineplus.gov/ency/article/000816.htm.

the formation of neoantigens or autoantigens that are recognized by the body's immune system. The body's inflammatory process creates antibodies in response. *Id*. at 23.[50]

The mother then described several mechanisms by which an environmental trigger may induce autoimmunity, beginning with molecular mimicry. Pet. Ex. 54 at 23.[51] The body's immune response to foreign antigens that "bear sufficient structural similarity to self-antigens" results in the activation of T cells that cross react with self-antigens. *Id*. Next, epitope spreading is where the "immune system expands its response beyond the original epitope recognized by T or B cells to induce the release of non-cross-reactive epitopes that are recognized by the immune system later." *Id*. at 23-24. Bystander activation occurs when foreign antigens "stimulate toll-like receptors and other pattern recognition receptors become activated in the inflammatory environment" causing the release of proinflammatory cytokines that may damage tissues or release antigens that activate autoreactive T cells. *Id*. at 24. Finally, polyclonal activation of B cells is due to persistent viral infection, where "monospecific clones can emerge, accompanied by very high levels of antibody production and the formation of circulating immune complexes . . . [and] may cause the autoimmune disease". *Id*.[52] The mother also included paragraphs related to "PNS", "PCD", "peripheral blood lymphocytes", and "anti-Hu syndrome" although the relevance of these excerpts is never stated and is unclear.[53] *Id*. at 25-27.

The mother next explained that autoimmune encephalitis occurs when the immune system "mistakenly attacks healthy brain cells, leading to inflammation of the brain." Patients may present with neurologic and psychiatric symptoms. Pet. Ex. 54 at 27.[54] She also included several excerpts related to "Autoimmune Epilepsy". *Id*. at 28.[55] Additionally, she provided a reference[56] that explains the disease process of autoimmune myasthenia gravis and quoted excerpts from an unknown source[57] regarding immune-mediated movement disorders. Neither source discusses vaccines. *Id*. at 28-32.

Finally, the mother cited an article[58] that discusses a potential link between autoimmunity and severe mood and psychotic symptoms. Pet. Ex. 54 at 33-34.

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[50] Aristo Vojdani, *A Potential Link Between Environmental Triggers and Autoimmunity*, 2014 AUTOIMMUNE DISEASES 1 (2014).
[51] *Id*.
[52] *Id*.
[53] The mother argued that petitioner's lumbar puncture showed pleocytosis with elevated white blood cells, evidencing that her nervous system "had been infiltrated." Pet. Ex. 54 at 25. The article she cited thereafter stated that pleocytosis appears in patients with PNS. *Id*.; Mikolaj Piotr Zaborowski & Slawomir Michalak, *Cell-Mediated Immune Responses in Paraneoplastic Neurological Syndromes*, 2013 J. OF IMMUNOLOGY RES. 1 (2013).
[54] The mother cited to Genetic and Rare Diseases Information Center, *Autoimmune Encephalitis*, https://rarediseases.info.nih.gov/diseases/11979/autoimmune-encephalitis.
[55] The mother cited to Epilepsy Foundation, *Autoimmune Epilepsy*, https://www.epilepsy.com/causes/autoimmune.
[56] Bastien Joubert & Jerome Honnorat, *Autoimmune Channelopathies in Paraneoplastic Neurological Syndromes*, 1848 ELSEVIER 2665 (2015).
[57] The embedded hyperlink for this source does not work.
[58] Giuseppe Quaranta et al., *Psychotic and Nonpsychotic Mood Disorders in Autoimmune Encephalitis: Diagnostic Issues and Research Implications*, 2 NEUROSCIENCES 228 (2015).

The mother detailed events which she claims occurred in petitioner's lungs immediately following petitioner's receipt of the varicella vaccine.[59] Pet. Ex. 54 at 20. The mother submits that upon arriving home after receipt of the varicella vaccine, petitioner had to use her inhaler and her sister's nebulizer for the next three days with some improvement. *Id*. Petitioner did not inform the mother of these symptoms and did not recall how soon after her vaccine she experienced the first asthma attack. Nevertheless, the mother submits that "it is possible that she initiated the first pMDI inhaler, within the first 30 min, because she report[ed] an 'asthma attack' soon after arriving home." *Id*. at 20-21. Petitioner then used the inhalers for over 48 hours since receiving the vaccine and until the mother observed petitioner's swollen airway and enlarged uvula within 72 hours of the vaccine. *Id*. at 21. Petitioner visited the ER within 72 hours of the vaccination. Thus, the mother concluded that "it is entirely possible and reasonable to deduct (sic) that the Petitioner was not only experiencing signs of ANAPHYLAXIS BEFORE 4 HOURS FOLLOWING VACCINATION, but, DID IN FACT CONTINUE to experience A BIPHASIC ANAPHYLACTIC REACTION THAT BECAME MORE SEVERE after 48 hours and before 72 hours post Vaccination." *Id*. at 21-22 (emphasis in original).

The mother claimed that the ER treaters failed to give petitioner the appropriate medication. They did not administer epinephrine but instead gave a solu-medrol injection. Pet. Ex. 54 at 22.

i. Respondent's Expert

a. Expert Report from Dr. Max Wiznitzer

Respondent submitted one report from Dr. Wiznitzer. Resp. Ex. A. Dr. Wiznitzer obtained his medical degree from Northwestern University and completed a fellowship in pediatric neurology at the Children's Hospital of Philadelphia thereafter. Resp. Ex. B.

Dr. Wiznitzer provided a detailed summary of petitioner's medical history. Resp. Ex. A at 1-10. Specifically, he documented petitioner's below average scores on academic testing, sensory disturbance, and evidence of abnormal attention prior to vaccination. *Id*. at 1-2. He also documented that petitioner "had no signs or symptoms of anaphylaxis" when she presented to the ER on July 5, 2013. *Id*. at 2; *see* Pet. Ex. 3.

Dr. Wiznitzer then summarized the letters submitted by petitioner's treaters Dr. Lacayo and Dr. McKean. Resp. Ex. A at 10-12.

Dr. Wiznitzer opined that petitioner had longstanding learning issues and fluctuating grades prior to 2013. Her IQ test between July 2013 at 91 and March 2016 at 87 showed "no significant difference". Her transient lower IQ measured in August 2014 can be explained by her mood and anxiety and known attention deficit disturbance, likely aggravated by her depression. Thus, there was "no evidence of an actual neurocognitive/IQ decline as opined by Dr. Lacayo." Resp. Ex. A at 12.

[59] The events she described are not contained in any medical record or petitioner's affidavit and were presented for the first time in this document. *See* Pet. Ex. 1.

Further, petitioner had long standing attention and anxiety disorders, described as a "sensory disturbance" in records from Cincinnati Children's Hospital in 2002, as well as throughout her psychiatric and psychological assessment records prior to her vaccination in 2013. Resp. Ex. A at 12. Contemporaneous medical records do not show any significant worsening in her cognitive function, learning skills, or mental health following her childhood MMR vaccine or her first varicella vaccine. Recurrent ear infections improved after her tonsils and adenoids were removed, though she did not have an abnormal number of annual infections for a child. *Id*.

Petitioner's emergency room visit on July 5, 2013 was not consistent with anaphylaxis. She had an acute infection with small throat exudate still found on examination a week later. Rather, her presentation was consistent with acute infection of strep. Further, even if it were anaphylaxis, it was outside the timeframe considered to be medically reasonable for a vaccine reaction. Resp. Ex. A at 12-13; Resp. Ex. A Tab 1 at 3.[60]

Petitioner complained of a tremor during her visit on July 2, 2013 and prior to her vaccination. The tremor was reported on July 18, 2013 as lifelong and unremarkable. In the fall of 2013, a differential diagnosis for her movements and mood disturbance included inborn error of metabolism or autoimmune encephalitis. Testing ruled out both, "leaving the likely diagnosis of psychogenic as the reason for the observed movements." Resp. Ex. A at 13. Another possible diagnosis was choreiform movements which are subtle neurologic signs that occur in those with developmental challenges but are not vaccine related. *Id*. Petitioner was diagnosed with functional neurological disorder (i.e. psychogenic disorder), which appeared several times in the medical records. In combination with the physical manifestations of her mental health disorders, a diagnosis of psychogenic disorder explains the fluctuating and, at times, non-physiological nature of her complaints. *Id*.

Dr. Wiznitzer addressed petitioner's behavioral changes observed around September 2013 that improved with lamotrigine and later in 2019 with fluoxetine. He opined that her behavioral changes and improvement with these medications were consistent with a diagnosis of psychogenic disorder. Resp. Ex. A at 13. Petitioner underwent extensive testing, which did not reveal any evidence of immune mediated causation. Although petitioner attempted to characterize her mood disorder as autoimmune encephalitis, her mood disorder was more likely the result of her ADHD and anxiety with increasing demands as she grew older. *Id*. She improved without intervention, which would not be expected if an autoimmune disorder were present. Specifically, her improvement with the use of an antidepressant would not be expected if it were autoimmune encephalitis. A "[m]ood disorder is a known comorbidity of ADHD that presents in the adolescent years." *Id*.

Dr. Wiznitzer further submitted that there was no support in the medical records for a diagnosis of epilepsy. Extended EEG testing showed "no EEG changes consistent with seizures in association with" any behavioral changes, such as staring/inattention, emotional changes, repetitive blinking, and focal twitching. Resp. Ex. A at 13. On August 19, 2015, epilepsy was ruled out at Emory based on a prolonged EEG. *Id*. at 13-14. Dr. Wiznitzer explained that "focal slowing in the left more than right temporal areas and sharply contoured waveforms" are nonspecific in etiology and occurred without clinical correlation. Epilepsy requires both a clinical description and

[60] 42 C.F.R. §100.3.

EEG correlate. *Id*. at 14. Here, the likely explanation for the EEG findings was her longstanding history of learning and attentional challenges which long predated the subject vaccine. *Id*.; Resp Ex. A Tab 3.[61]

Dr. Wiznitzer pointed to the objective testing that showed no evidence of immune mediated cerebral injury, autoimmune or infectious encephalitis, or any brain injury at all. Two MRIs in 2014 were normal with no evidence of acute or remote brain injury. Extensive testing for autoimmune antibodies was negative. Lumbar puncture found no evidence of inflammatory process. Resp. Ex. A at 14. Dr. Wiznitzer addressed Dr. Lacayo's conclusion that petitioner had encephalitis based on an elevated albumin level, explaining that this conclusion was flawed because Dr. Lacayo failed to recognize that it is CSF protein—not serum albumin—that is the potential marker for encephalitis; petitioner's CSF protein was normal. *Id*.; Resp. Ex. A Tab 4.[62] Dr. Wiznitzer further noted that petitioner had no clinical features consistent with encephalitis as noted by her treating physicians. Regardless, this testing was done two years after the vaccination, so any findings could not be ascribed to the vaccination even if they had been abnormal. Resp. Ex. A at 14.

Dr. Wiznitzer contends that petitioner experienced no worsening/exacerbation of her immune deficiency between 2013 and 2019 until she was pregnant and when IgG levels are known to decrease. Resp. Ex. A at 14; Resp. Ex. A Tab 5.[63]

Dr. Wiznitzer discussed petitioner's diagnosis of MG in 2019, noting that she had a positive acetylcholine receptor antibody titer in 2015 with no clinical correlate. In 2019, she had subjective complaints of fatigue/weakness but no muscle weakness on examination and borderline single fiber EMG results. Resp. Ex. A at 14-15. Her breathing complaints improved with her asthma treatments, which is not typical for MG-associated breathing problems. Even so, the diagnosis of MG was more than five years after the subject vaccination and without biological process to explain the association; thus, her MG is also unrelated to the subject vaccine. *Id*. at 15.

Further, Dr. Wiznitzer noted that petitioner had no features of encephalitis/meningitis that can be attributed to either wild type varicella virus or the vaccine. He addressed Dr. Lacayo's reliance on the list of adverse reactions post marketing for Varivax vaccine, noting that Dr. Lacayo did not include the sentence before that list in the insert that states that the listed adverse events "are reported voluntarily from a population of uncertain size, [so] it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure." Resp. Ex. A at 15 (emphasis in original). Dr. Wiznitzer concluded that "[s]ince a causal relationship cannot be established, the significance and applicability of the reported events cannot be used to prove a cause-effect relationship." *Id*.

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[61] Selim R. Benbadis, *The EEG in Nonepileptic Seizures*, 23 J. OF CLINICAL NEUROPHYSIOLOGY 340 (2006), filed as "Resp. Ex. A Tab 3."

[62] Tania Cellucci, MD, MScCH et al., Clinical Approach to the Diagnosis of Autoimmune Encephalitis in the Pediatric Patient, 7 NEUROLOGY NEUROIMMUNOLOGY & NEUROINFLAMMATION e663 (2020), filed as "Resp. Ex. A Tab 4."

[63] Zhang Tingting et al., *Changes of Serum Immunoglobulin Level in Healthy Pregnant Women and Establishment of Its Reference Interval*, 46 J. OF CENT. S. U. (MED. SCI.) 53 (2021), filed as "Resp. Ex. A Tab 5."

In concluding, Dr. Wiznitzer opined that no evidence exists in the record that the July 2, 2013 varicella vaccination caused or aggravated any of petitioner's conditions. Neither Dr. Lacayo nor Dr. McKean offered a plausible medical theory that reliably links her vaccinations to any of her medical conditions. In short, "there is no evidence that any of [petitioner's] vaccinations had any adverse impact on her health." Resp. Ex. A at 15.

III. The Parties' Arguments

A. Respondent's Motion to Dismiss

Respondent filed his motion to dismiss on March 4, 2020. He noted that petitioner alleged that she suffered from "a seizure disorder, cerebral injury, Major Neurocognitive Disorder, athetosis, chorea, and/or neurologic, physchiatric (sic), and physical impairments and other injuries that were 'caused-in-fact'" by the varicella vaccine received on July 2, 2013. Resp. Motion at 1; Petition at 1. Respondent moved to dismiss on the grounds that petitioner has failed to prove her varicella vaccination was the cause-in-fact of any of her alleged injuries. Resp. Motion at 1.

Respondent summarized the procedural history, including the Pro Se Report the mother filed on December 5, 2019. Resp. Motion at 2-3; Pro Se Report. After summarizing petitioner's medical history, respondent provided the legal requirements for how a vaccine claim may be proven, i.e. as an On-Table claim or as causation-in-fact claim requiring a petitioner to satisfy all three *Althen* prongs. Resp. Motion at 11-12.

Respondent argued that it is the petitioner's burden to prove that she suffered a vaccine related injury and petitioner's claims alone are not sufficient. Resp. Motion at 12. A petitioner's claims must be supported by the medical records and/or a credible expert opinion. *Id*.; § 13(a)(1); *Lett v. Sec'y of Health & Human Servs*., 39 Fed. Cl. 259, 262-63 (1997). Here, although petitioner believes she suffered from a vaccine related injury, her references to the record are unpersuasive and it is unclear that she even suffered the injuries she alleged. Resp. Motion at 12; *see Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1343, 1352-53 (Fed. Cir. 2011); *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339 (Fed. Cir. 2010).

Respondent addressed Dr. Lacayo's records documenting "the cause and effect relationship with [her varicella] vaccine is not known" which he discussed with petitioner's pediatrician. Resp. Motion at 13; Pet. Ex. 2 at 5, 8. Dr. Dyer was similarly unable to provide a specific connection or diagnosis supported by the DSM-5, other than to write "evidence suggests a causative link between vaccinations and periods of cognitive decline". Resp. Motion at 13; Pet. Ex. 6 at 6. During petitioner's visit on July 3, 2018, five years later, Dr. Lacayo wrote that the onset of petitioner's tremors "could have been immune-related reaction to live vaccine", but his reasoning seemed "odd" in light of his prior skepticism about a potential link between the vaccination and petitioner's health. This conclusory opinion is unpersuasive. Resp. Motion at 13; Pet. Ex. 40 at 21. Respondent argued that physicians' conclusions are only as good as the evidence that supports them. Resp. Motion at 13; *Davis v. Sec'y of Health & Human Servs*., 20 Cl. Ct. 168, 173 (1990); *see also Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010). Thus, Dr. Lacayo's conclusory opinion is unpersuasive. Resp. Motion at 13. Respondent argued

that none of the treating physicians "provide[d] a medical theory, much less a logical sequence of cause and effect showing how the vaccination caused petitioner's injuries." *Id*. at 13-14.

Respondent highlighted the various notations in the record which were based on "assertions made by petitioner's mother." Resp. Motion at 14. At the ER on July 5, 2013, the mother reported that petitioner was having an allergic reaction to the varicella vaccine. *Id*.; Pet. Ex. 3 at 2-3. The medical record documents no signs of anaphylaxis. *Id*. Nevertheless, on August 3, 2015, the mother reported to Dr. Helmers that petitioner had an "anaphylactic reaction" three days after the varicella vaccine. Resp. Motion at 14; Pet. Ex. 9 at 33. In March of 2014, the mother reported to the pediatrician that Dr. Lacayo attributed petitioner's symptoms to the varicella vaccine. Resp. Motion at 14; Pet. Ex. 2 at 5. The pediatrician then telephoned and confirmed with Dr. Lacayo that Dr. Lacayo was unsure of the relationship. *Id*.

Further, respondent detailed other inconsistencies of purported vaccine injuries reported to various providers. In her first visit with Dr. Lacayo, petitioner and the mother reported hand tremors since birth. Resp. Motion at 14; Pet. Ex. 2 at 14-16. In January 2016, petitioner and the mother reported that the tremors began two years ago, after[64] the subject vaccination. Resp. Motion at 14; Pet. Ex. 12 at 24. They also reported to Drs. Dyer, Helmers, and Rivner that petitioner developed tremors shortly after the vaccination. Resp. Motion at 14; Pet. Ex. 6 at 2; Pet. Ex. 9 at 33; Pet. Ex. 12 at 65.

Respondent concluded that, without an expert report that explains how the varicella vaccination caused petitioner's injuries, petitioner is unable to meet her burden of proof. Resp. Motion at 14. Petitioner's Pro Se Report, in which the mother submitted her own opinions, is insufficient. The mother is not a medical expert in this case, nor is she qualified to opine on issues of medical causation. *Id*. at 14-15. Further, the Pro Se Report does not contain a medical theory or offer a logical sequence of cause and effect. *Id*. at 15. At best, the Pro Se Report can be construed as legal argument. Without an expert addressing the *Althen* prongs, petitioner has failed to establish entitlement and the case should be dismissed. *Id*.

B. Petitioner's Response

Petitioner filed a response on March 1, 2021, in which the mother stated that "[i]t is the full intention of the petitioner to show by preponderance of evidence" that the vaccine caused petitioner's injuries. Pet. Response, ECF No. 77-1. Throughout the response, the mother inaccurately referenced arguments made by respondent in his Motion to Dismiss as findings of the Court. *Id*. at 2, 10, 12, 17-18, 22, 24-25, 26, 27, 31, 32, 33-34, 41-42, 44-45.[65] Additionally, the mother seems to conflate the Court's role with petitioner's burden in prosecuting and proving her own claims. *Id*. at 5 (The mother wrote that the court "did not reach out to [Dr. McKean] to explain

[64] Respondent stated that petitioner and the mother reported hand tremors two years prior to the vaccination. Resp. Motion at 14. However, the medical record he cited reflects that they reported the tremors began two years prior to the visit, *after* the vaccine. *See* Pet. Ex. 12 at 24.

[65] For example, the mother submitted that "The court charges that the petitioner has not met her burden of proof" and that "The court falsely claims to not be able to find a vaccine related injury or death that occurred and implies that any claims of injuries is or has been (sic) based solely upon the claims of the petitioner." Pet. Response at 2. She later argued that "The court again misrepresents the facts and the truth by stating, 'the ER did not find any signs or symptoms of anaphylaxis.'" *Id*. at 27.

prongs and the Althen criteria."). Petitioner's response relied on both the mother's "expert report" and the Pro Se Report. *See* Pet. Ex. 54; Pro Se Report.

The mother argued that petitioner's medical records and physicians substantiate her claims of various injuries, including but not limited to major neurocognitive disorder, myasthenia gravis, epilepsy, complex partial seizures, neurological immune mediated brain injury, major depressive disorder, borderline personality disorder, dementia, and encephalitis. Pet. Response at 3-9. She contended that preponderant evidence shows that petitioner suffered at least twenty-one injuries since the 2013 varicella vaccine, in addition to "countless more injuries identified from the multiple ways those injuries have negatively impacted" her life. *Id*. at 10-11. The mother then included portions of the medical records—without any citations—to support the claims of petitioner's numerous injuries.

The mother referenced Dr. Lacayo's written opinion dated April 26, 2016, arguing that it, in combination with information from the CDC and the vaccine package insert, is sufficient to prove causation. Pet. Response at 22-25; *see also* Pet. Ex. 10. She concluded that "[m]uch data have been gathered that more than suggested a correlation between the petitioners (sic) immunodeficiency and her poor response to the live vaccine entering her body." Pet. Response at 26.

Finally, the mother expressed her discontent with the healthcare system in the United States, as physicians have little time with patients, records are difficult to access, and quality physicians willing to treat rare conditions are difficult to come by. She also discussed the impact petitioner's various conditions have had on her and the rest of her family. Pet. Response at 38-46.

IV. Applicable Law

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

To prove causation for an "off-Table" injury, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination

and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. The first *Althen* prong requires petitioners to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioners' "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccinations can cause the injury, petitioners must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). Petitioners are not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

To satisfy the third *Althen* prong, petitioners must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the

temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

A. Legal Standard Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs*., 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioners after-the-fact. *See Gerami v. Sec'y of Health & Human Servs*., No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co*., 333 U.S. 364, 396 (1948).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining facts such as the onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs*., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

There are situations in which compelling oral testimony may be more persuasive than written records. *See Campbell*, 69 Fed. Cl. at 779. When witness testimony contradicts medical records, such testimony must be consistent, clear, cogent, and compelling to be persuasive. *See Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (vacated on other grounds, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs*., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020), *review denied, Sanchez by & through Sanchez v. Sec'y of Health & Hum. Servs*., 152 Fed. Cl. 782 (2021)) (quoting *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)); *see, e.g., Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs*., No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were

consistent with the other factual evidence"). Special masters may also consider other types of evidence, such as unsworn statements, on the grounds that the Vaccine Program was designed to have "flexible and informal standards of admissibility of evidence." 42 U.S.C. § 300aa-12(d)(2)(B); *see also Munn v. Sec'y of Health & Human Servs*., 970 F.2d 863, 873 (Fed. Cir. 1992).

In short, "the record as a whole" must be considered. § 13(a).

B. Evaluating Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). And nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

C. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the literature and articles in detail, the undersigned reviewed and considered all of the medical literature and articles submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

V. Discussion

Although respondent filed a Motion to Dismiss the petition, the submission is more comparable to a Motion for Ruling on the Record consistent with Vaccine Rule 8(d), as he details petitioner's medical history and makes factual and legal arguments as to why petitioner's claim

should be dismissed. Petitioner was afforded an entire year in which to respond to respondent's motion. Consistent with Vaccine Rule 3, I find that petitioner was given a full and fair opportunity to present her case and develop the record.

Because petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, petitioner must show by preponderant evidence that she suffered at least one defined and recognized injury and that the injury was caused by the vaccination at issue. *Capizzano*, 440 F.3d at 1320. Although there is support for some of the diagnoses alleged, petitioner failed to prove that they were caused by the subject vaccine.

A. Defined and Recognized Injuries

An initial step in an off-Table claim is to "determine what injury, if any, was supported by the evidence presented in the record". *Lombardi*, 656 F.3d at 1353. The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury." Further, "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *Broekelschen*, 618 F.3d at 1346 (explaining that a vaccine-related injury "has to be more than just a symptom or manifestation of an unknown injury."); *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014) ("[I]f the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the *Althen* test for causality."). Thus, petitioner has the burden to demonstrate a medically-recognized injury that she suffers from. *Broekelschen*, 618 F.3d at 1348; *see also Lasnetski v. Sec'y of Health and Human Servs.*, 128 Fed. Cl. 242 (2016).

When determining whether petitioner has adequately proven a demonstrable injury, special masters analyze petitioner's complete medical records filed into the record. § 11(c)(2). Contemporaneous medical records created at the time of treatment are generally considered to be trustworthy and are typically afforded more weight than statements made later, particularly when there is a conflict between the two. *Cucuras,* 993 F.2d at 1528; *Kirby,* 993 F.3d at 1382-83; *Gerami,* No. 12-442V, 2013 WL 5998109, at *4.

Here, respondent argues that petitioner has failed to meet her burden of showing at least one defined and recognized vaccine related injury. Resp. Motion at 12-13. Petitioner argues that she suffered over 21 injuries caused by the varicella vaccination she received on July 2, 2013. *See generally* Pet. Response.

i. Injuries allegedly caused by the varicella vaccination that are unsupported by the record

In support of her claim, petitioner relied on letters from two of her treating physicians. Pet. Ex. 10; Pet. Ex. 11; Pet. Ex. 41. Dr. Lacayo wrote in a letter dated April 26, 2016, that petitioner first presented on July 18, 2013 with "dance like tremors" and the only triggering mechanism was a vaccine. Thereafter, petitioner's condition deteriorated with poor school performance and behavioral changes. An EEG showed lateralized abnormality with epileptiform discharges. Pet. Ex. 10 at 1. She was prescribed Lamictal from January to June of 2014 to stop subclinical seizures. She was evaluated by psychiatry and could not maintain enrollment in school. Her EEG was

improved "when seizure medication was increased to FDA-approved maximum dosage." *Id*. However, she continues to require treatment for neuro-psychiatric disorders including but not limited to alteration in awareness and unspecified tremors. *Id*. She has recently been diagnosed with immune deficiencies, which explains why her neurological system responded adversely to live vaccines. *Id*. Dr. Lacayo did not refer to any definitive diagnoses, made general statements about her conditions, and failed to reference the medical records in support of any of his opinions.

In a second letter dated January 25, 2021, Dr. Lacayo expressed the same opinion but added more detail to petitioner's medical history. Pet. Ex. 41. He then listed ten diagnoses petitioner allegedly received since 2013. *Id*. at 2-3. Again, Dr. Lacayo failed to cite to any medical records or objective testing to support any of his statements/opinions. He did, however, discuss his collaboration with the mother when drafting the second letter, writing that upon "further history taking between myself and her mother . . . I concluded that there was a similarity in her current functional decline compared to what her mother noted following a MMR vaccine at the patient's age of 5." *Id*. at 2. At no time did Dr. Lacayo indicate that he reviewed petitioner's medical records from childhood; rather, he relied on the mother's recollection of her medical history.

Petitioner also provided a letter from her treating allergist, Dr. McKean, dated May 13, 2016. Dr. McKean wrote that petitioner has primary immune deficiency—specifically IgA, IgM, and Mannose Binding Lectin Deficiency—that was not discovered before she received the varicella vaccine. Pet. Ex. 11 at 1. He further wrote that she had a "decline in cognitive function and other neurologic symptoms following the vaccine." *Id*. Dr. McKean failed to provide any evidence explaining primary immune deficiency, what causes it, or any evidence connecting it to petitioner's varicella vaccine.

In her submission, the mother detailed petitioner's medical history and provided various webpages and articles that discuss a host of conditions. *See generally* Pet. Ex. 54; Pro Se Report; Pet. Response. In her "expert report", the mother listed ten diagnoses that petitioner received that were "new onset" after her receipt of the varicella vaccine. Pet. Ex. 54 at 5. In her Pro Se Response to respondent's Motion to Dismiss, she claimed that petitioner suffered "21 identified injuries". Pet. Response at 10-11. The mother failed to provide any references to test results or treating physician opinions that confirmed the claimed diagnoses.

The majority of the claimed diagnoses are either inconsistent with the contemporaneous medical records or are not cognizable injuries. For the most part, petitioner's medical records discussed symptoms or diagnoses reported by the mother and petitioner, as opposed to diagnoses rendered by petitioner's actual providers. As a general matter, a patient's reporting of a diagnosis is not the same as a physician or treating provider diagnosing a patient with a particular condition or illness. *See, e.g., Rothenberg v. Sec'y of Health & Human Servs*., No. 15–696V, 2018 WL 2731639, at *16 (Fed. Cl. Spec. Mstr. Apr. 19, 2018).

Dr. Lacayo's letters are inconsistent with petitioner's medical history and contrary to his office records. Thus, his opinions are unsubstantiated and fail to prove that petitioner suffered from any definable injuries associated with the varicella vaccine. *See R.K. v. Sec'y of Health & Human Servs.*, 125 Fed. Cl. 57 (2016), *aff'd,* 671 Fed. Appx. 792 (Fed. Cir. 2016) (affirming a special master's determination that a petitioner failed to establish a definitive diagnosis after the special

master heard contradictory testimony from petitioner's expert). Dr. McKean wrote that petitioner had a "decline in cognitive function and other neurologic symptoms following the vaccine." Pet. Ex. 11. Dr. McKean failed to define any cognizable injury or objective testing upon which his opinion was based. *See Broekelschen*, 618 F.3d at 1346. Neither doctor referred to any of petitioner's medical records showing any definable injuries associated with the varicella vaccine. The mother's submissions listed many conditions, most of which were ruled out by clinical impression or objective testing. Thus, in discussing the specific conditions and injuries claimed to be vaccine related, I afford more weight to the contemporaneous medical records.

The mother alleged that petitioner suffered an anaphylactic reaction within an hour and/or within 72 hours of the subject vaccination. Pet. Ex. 54 at 20-21. Specifically, the mother claimed in the Pro Se Report that petitioner self-treated for an asthma attack by using her own and her sister's inhalers within 24 hours of receiving the vaccine, without the mother's knowledge. *Id*. This course of events was not reported to any provider at any time, including at the ER. Further, this information is not contained in petitioner's own affidavit. *See* Pet. Ex. 1. Upon presentation to the ER on July 5, 2013, the mother reported an allergic reaction, breathing difficulty, and a varicella vaccine received 4 days ago. Pet. Ex. 3 at 2, 10. Following examination, the ER record specifically documented that petitioner showed "no signs or symptoms of anaphylaxis" and was in "no apparent distress"; her "[a]irway was patent [with] mildly swollen uvula". Overall, her "[r]espiratory effort [wa]s even, unlabored", and she did "not display signs of respiratory distress". *Id*. at 2, 3, 8. She was diagnosed with and treated for a viral infection and was subsequently discharged. *Id*. at 6, 11. A follow up appointment with Groff on July 12, 2013 revealed continuing mild exudate on the left side of her throat, but otherwise the examination was normal/negative. Pet. Ex. 2 at 24. Anaphylaxis occurring within four hours of vaccination is an On-Table injury. 42 C.F.R. §100.3. There is no corroborating evidence that petitioner had an anaphylactic reaction whatsoever, much less one that occurred within four hours of the vaccine.

The medical records also do not support the alleged diagnoses of seizures, epilepsy, brain injury, encephalitis, encephalopathy, or cerebral dysfunction following the subject varicella vaccine. Pet. Ex. 5 at 18 (MRI performed in January 2014 was normal with no brain injury noted); Pet. Ex. 9 at 8-9, 25-26, 37, 40 (MRI performed at Emory in July 2014 was normal; epilepsy was ruled out at Emory following long term video EEG); Pet. Ex. 12 at 55 (MRI performed in December 2015 was normal, showing "[n]ormal signal characteristics and morphology" in the cerebellum); Resp. Ex. A at 13-14 (focal slowing seen on EEG was determined to be non-specific in etiology). Despite Dr. Lacayo's suspicion of seizure disorder in the left hemisphere based on EEGs he reviewed, he later wrote that long term monitoring at Emory showed no overt seizures and her neurological examination conducted by him was normal/negative. Pet. Ex. 5 at 1-2, 6, 11-12, 17, 20. Dr. Lacayo also wrote, "[i]t is unclear how much psychological issues are contributing to [her] spells." *Id.* at 3. In a separate handwritten form, Dr. Lacayo documented a normal, intact neurological examination. *Id*. at 39. An examination and testing performed by Dr. Silver at Emory was negative/normal. Pet. Ex. 9 at 16-17. At a subsequent visit, Dr. Silver wrote that it was unclear whether her problems were organic, as EEG showed no epileptiform activity and MRI was normal. *Id*. at 18, 19, 25-26, 37-38, 40. He also noted that Lamictal "clearly helped her but of course this has great psychiatric benefits as well." *Id*. at 23. Dr. Silver later added, "[o]n the urging of her mother…exhaustive workup for causes" had been done with the most likely causes excluded. *Id*. at 29. Objective testing performed in December 2015 did not show antibodies to "any component

of the autoimmune encephalitis." Pet. Ex. 12 at 37, 49; Pet. Ex. 4 at 1. Further, Dr. Morgan noted in January 2016 that her presentation was not consistent with encephalitis or encephalopathy. Pet. Ex. 12 at 29. Rather, his impression based on neuropsychological testing was that her pattern of cognitive deficits was "nonspecific with regard to etiology" and inconsistent with limbic (anti-NMDA receptor) encephalitis. *Id*. at 12. In April 2016, Dr. Morgan noted a normal neurological examination. *Id*. at 5-8. Thus, based on the medical records and objective testing performed, petitioner has not been diagnosed with seizures, epilepsy, brain injury, encephalitis, or encephalopathy. The only support for cerebral dysfunction or deficits in petitioner's left brain function are attributed to the mother's reporting of a finding by Dr. Cates in 2004. However, Dr. Cates did not mention these deficits in his letter filed into the record, and he specifically noted that his examination of petitioner was for academic purposes alone and not medical purposes. Pet. Ex. 33 at 53; *see* Pet. Ex. 26.

There is no definitive diagnosis of dementia. Pet. Ex. 12 at 65, 70. On October 21, 2015, petitioner presented to Dr. Rivner reporting a history of a 2013 vaccine which caused difficulty breathing, swollen throat and uvula thought to be strep, subsequent development of bilateral arm tremor diagnosed as athetosis, acting strange, mental problems—all reportedly thought to be autoimmune encephalopathy. *Id*. at 65. Dr. Rivner's impression that day was possible autoimmune encephalitis manifested by seizures, athetosis, personality changes, and dementia. *Id*. at 70-71. It is unclear what Dr. Rivner based this impression on other than the mother's history of symptoms. A MoCA score of 27 was noted, but it is unclear from the record if the MoCA score was information the mother provided to Dr. Rivner or if his office administered the test that day. *Id*. at 65. Moreover, a MoCA score of 26 or better is considered normal.[66] Petitioner scored a 27. Pet. Ex. 12 at 65. The mother later reported to Dr. McKean in March 2016 that MoCA testing showed dementia. Pet. Ex. 4 at 1. Without further explanation and this being the only mention of dementia by any provider in the medical records filed, preponderant evidence does not support a diagnosis of dementia.

Likewise, based on the medical records, the diagnoses of MG and immunodeficiency are dubious. Two years after receipt of the subject varicella vaccine, petitioner was found to have high levels of antibodies to acetylcholine on lab work in the summer of 2015. But because she was asymptomatic, she was not diagnosed with MG at that time. Pet. Ex. 9 at 29; Pet. Ex. 4 at 12, 16. Laboratory testing also showed sufficient protective antibodies for tetanus toxoid and diphtheria—presumably from prior vaccination—but antibodies to varicella zoster (IgM and IgG) were low. *See generally* Pet. Ex. 14. Dr. McKean diagnosed petitioner with selective IgA and IgM immunodeficiency in March 2016. Pet. Ex. 4 at 2. In March 2019, Dr. Rivner diagnosed petitioner with myasthenia gravis due to abnormal test results despite presenting with "very atypical" symptoms. Pet. Ex. 38 at 3, 5, 7. Although these diagnoses are questionable, there is some evidentiary support that petitioner has immunodeficiency and myasthenia gravis. In any event, her immunodeficiency was diagnosed in March 2016—nearly three years after vaccination—and her MG was diagnosed in March 2019—nearly six years after vaccination. It is unknown whether these conditions pre-dated the vaccination or occurred at some point years after the receipt of the subject vaccination around the time they were diagnosed. Pet. Ex. 4 at 2; Pet. Ex. 38 at 3; Pet. Ex. 39 at 3; Pet. Ex. 40 at 4-5.

[66] *Supra*, note 31.

In addition, the mother alleged petitioner received several psychiatric diagnoses. At petitioner's initial assessment with Dr. Norniella in April 2014, she was assessed as having severe mood swings, possibly caused by seizures, bipolar disorder, or borderline personality disorder. Pet. Ex. 8 at 17. No definitive diagnosis was made, but Dr. Norniella related the symptoms described to him by petitioner and the mother to several *potential* diagnoses. This isolated notation in the medical records is insufficient to support a definitive diagnosis of either bipolar disorder or borderline personality disorder. Both diagnoses appeared in Dr. Dyer's medical records, but she documented that Dr. Norniella diagnosed petitioner with "Dissociative Identity Disorder, Temporal Lobe Epilepsy with Behavioral Changes, Vaccine Injury/Brain Injury, Rapid Cycling Bipolar Disorder, and Borderline Personality Disorder, *as provided by [the mother]*." Pet. Ex. 6 at 2 (emphasis added). None of the diagnoses reported by the mother are contained in Dr. Norniella's records. Much like Dr. Dyer's records, mentions of these diagnoses in Dr. Norniella's records appear to be based on reports from petitioner or the mother—if they appear at all. *See generally* Pet. Ex. 8. Likewise, any mention of bipolar or borderline personality disorder contained in the Emory records are found in the reported medical history provided by the mother but not in the findings. Pet. Ex. 9 at 14, 19; *see also* Pet. Ex. 45.1 at 7 (hospital records from 2019 documenting a diagnosis of—among several other things—"Bipolar disorder, unspecified (HC)" that was present on admission; the source of these diagnoses is not clear, and some of the diagnoses listed were previously ruled out). Further, there is no support in the records that any testing resulted in diagnoses of either psychosis or schizophrenia. *See generally* Pet. Ex. 7. The only mentions of either diagnosis came from reports of petitioner or the mother. Pet. Ex. 9 at 15; Pet. Ex. 40 at 7, 11, 15, 19. Dr. Morgan's neuropsychological evaluation in March 2016 showed deficits in attention and concentration and reduced mental processing speed. Pet. Ex. 12 at 11. Intellectual function was average to low average while reading was borderline, with mild symptoms of depression. *Id*. The pattern of cognitive deficits was "nonspecific with regard to etiology" but most commonly seen in patients with significant psychiatric disorders. *Id*. at 12. There were multiple symptoms of significant personality disorder with many borderline traits on testing, but she was not administered a personality test that day. Dr. Morgan's diagnostic impression was unspecified mild neurocognitive disorder. *Id*. Thus, the objective evidence is insufficient to show that petitioner was diagnosed with bipolar disorder, borderline personality disorder, schizophrenia, or psychosis.

The mother also claimed that petitioner had extreme behavioral changes following the vaccine. Pet. Response at 17, 23; Pet. Ex. 54 at 6, 27, 28; Pro Se report at 19-21. The mother seems to argue that the behavioral changes were caused by autoimmune epilepsy, immune-mediated encephalitis, and immunologically mediated dementia. *See id*. For the reasons detailed above, I do not find any persuasive evidence in the record that petitioner was diagnosed with any of these conditions. Further, behavioral issues or changes on their own are *symptoms* and do not themselves amount to a diagnosis of a *defined injury*. Part of what is required under the Vaccine Act is that petitioner show by preponderant evidence that she suffered from a medically recognized injury, "not merely a symptom or manifestation of an unknown injury." *Lombardi*, 656 F.3d at 1353. As such, any behavioral issues or changes petitioner may have exhibited following the subject vaccine do not amount to a defined and recognized injury.

Notably, petitioner's childhood was replete with constant testing for various medical and psychological issues, the majority of which showed normal results. However, conditions continued

to be reported to various providers even though they had been ruled out. *See, e.g.*, Pet. Ex. 33 at 6-21, 27-28, 53; Pet. Ex. 18 at 2, 7; Pet. Ex. 15 at 8-9. As evidenced by the records filed and described above, this pattern continued throughout petitioner's life, even seen in her most recent records filed when she was a legal adult. The contemporaneous medical records themselves, as well as extensive objective test results, lack support for most of the injuries the mother claimed occurred as a result of the subject vaccine.

ii. Injuries allegedly caused by the varicella vaccine that pre-dated or arose years after petitioner's receipt of the varicella vaccine

The medical records confirm that petitioner was diagnosed with an unremarkable essential tremor that predated the subject vaccination. Pet. Ex. 2 at 18, 43; Pet. Ex. 5 at 6, 11, 12-15; Pet. Ex. 9 at 29; Pet. Ex. 12 at 5-8, 28. As more specifically described above, petitioner's questionable diagnosis of myasthenia gravis arose years after her receipt of the varicella vaccines with laboratory work revealing AChR antibodies. She was asymptomatic until at least 2019 when she received the diagnosis despite atypical symptoms. Pet. Ex. 4 at 1, 12, 16; Pet. Ex. 9 at 25, 29; Pet. Ex. 12 at 10, 25, 65, 70; Pet. Ex. 38 at 3; Pet. Ex. 39 at 7. Dr. McKean believed her fatigue was due her testing positive for HHV-6—not related to MG. Pet. Ex. 4 at 6; Pet. Ex. 14 at 4. As such, the medical records support these diagnoses, but the timing of the symptoms/diagnoses will be discussed further below.

Petitioner also received diagnoses for an unspecified anxiety disorder shortly after vaccination in July 2013; unspecified mood disorder during her time at Ridgeview Institute in April 2014; and major depressive disorder in June 2015. Pet. Ex. 6 at 16; Pet. Ex. 7a at 2-4; Pet. Ex. 13 at 3-4. Finally, the medical records support that petitioner received a diagnosis of a major neurocognitive disorder of unspecified origin by Dr. Dyer in August 2014 and unspecified mild neurocognitive disorder during her adult neuropsychological testing in March 2016. Pet. Ex. 6 at 6; Pet. Ex. 12 at 12. Notably, petitioner underwent the March 2016 neuropsychological exam "with regard to two episodes of behavioral changes noted after receiving MMR and varicella vaccinations"; Dr. Morgan, who administered the exam, wrote, "this pattern of cognitive deficits . . . is by far most commonly obtained in patients with significant psychiatric disorders." Pet. Ex. 12 at 10-12.

Based on the above analysis and appropriate weighing of the contemporaneous medical records, the diagnoses supported by the medical records are unremarkable essential tremor, myasthenia gravis, HHV-6, unspecified anxiety disorder, unspecified mood disorder, major depressive disorder, and unspecified neurocognitive disorder. The question becomes whether any of these conditions were caused by the varicella vaccine petitioner received on July 2, 2013.

B. Petitioner Has Failed to Meet Her Burden Under *Althen*

Althen requires that petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v.*

Sec'y of Health & Human Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Petitioner in this case fails on all three prongs.

i. Althen Prong I

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his or her claim. *Lampe*, 219 F.3d at 1361; *see also Caron v. Sec'y of Health & Human Servs*., No. 15–777V, 2017 WL 4349189, at *10 (Fed. Cl. Spec. Mstr. Sept. 7, 2017) (denying entitlement and dismissing a petition where the petitioner failed to provide an expert report to support her claim that the vaccinations caused her son's injuries and the medical evidence did not support her claim), *aff'd*, 136 Fed. Cl. 360 (2018).

A special master may also reject an expert's theory if the special master determines the expert lacks the requisite expertise in a certain medical specialty to authoritatively opine on the subject. *Veryzer v. Sec'y of Health and Human Servs.*, 98 Fed. Cl. 214, 224-25 (2011) (determining the special master's rejection of petitioner's expert was proper on the ground that she lacked the requisite expertise in in the subject on which she was asked to opine); *see also Gardner-Cook v. Sec'y of Health and Human Servs.*, 59 Fed. Cl. 38, 48 (2003) (affirming a special master's finding that petitioner's expert was not "capable of offering an expert opinion on an alleged neuroimmunological disorder" when the expert had never practiced neurology).

As detailed above, petitioner provided letters from two treating providers, wherein they stated that the varicella vaccine caused petitioner's injuries.

In his first letter, Dr. Lacayo concluded that "the vaccine in [his] medical opinion can be the causation of her symptomology." Pet. Ex. 10 at 1. In his second letter, Dr. Lacayo opined that "immune-logically abnormal patients may experience more adverse effects and are at a higher risk of adverse effects" from live attenuated vaccines like varicella. Pet. Ex. 41 at 2. Dr. Lacayo added that encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barre syndrome, Bell's Palsy, ataxia, non-febrile seizures, aseptic meningitis, meningitis, dizziness, and paresthesia are contained in the adverse event reporting section of the varicella vaccine package insert. *Id*.

Dr. Lacayo failed to articulate a medical theory connecting the vaccine to any injury, much less to any injury suffered by petitioner. He simply listed the adverse events contained in the package insert and concluded that the vaccine "can be the causation". Pet. Ex. 10 at 1. He further failed to explain how or why an immunocompromised individual is at higher risk of adverse effects from a live vaccine or the basis for his opinion that petitioner was immunocompromised prior to

receipt of her vaccination. Further, he relied on the package insert which generally has been given little weight in determining causation, as package insert adverse events consist of post-marketing reports based on temporal relationship with the receipt of the vaccine regardless of causality.[67]

Dr. McKean did not submit a theory of how the varicella vaccine could cause any of petitioner's alleged conditions. *See generally* Pet. Ex. 11. He simply stated that a live vaccine like varicella presents a risk to a patient with immune deficiency. *Id*. at 1. The mother conceded that Dr. McKean's letter did not provide a "mechanism by which the vaccine does in fact harm primary immune deficiency patients" because no one knows the mechanism. Pet. Ex. 54 at 7. Petitioner need not prove scientific certainty to satisfy prong I; she merely needs to provide a sound and reliable medical theory based on more than timing alone that connects the vaccine to her condition(s). Both Dr. Lacayo's and Dr. McKean's conclusory assertions are based solely on temporal association and an inaccurate medical history, which is insufficient to satisfy petitioner's burden under *Althen*. *See* Pet. Ex. 11.

Finally, the mother relied on "the CDC, ACIP and the Varicella Vaccine Manufacturers" to establish the *Althen* prongs, specifically prongs I and II. The mother detailed diagnoses she claimed petitioner had that were unsupported by the medical records. Summarily, based on her literature search, the mother argued that petitioner has a Primary Immune Deficiency and that live vaccines such as MMR and varicella are contraindicated for immunocompromised persons. Pet. Ex. 54 at 2-3.[68] She failed to cite to any evidence in the record to show that petitioner suffered from an immune deficiency prior to or at the time she received the subject vaccination. Any immune deficiency that petitioner may have was diagnosed roughly three years after her receipt of the subject vaccination. Pet. Ex. 4 at 1-2.

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[67] Special masters have not given manufacturers' package inserts much weight. One special master went so far as to declare that "federal regulations specifically preclude the contents of drug product labels, as reproduced in the [Physician's Desk Reference], from serving as admissions regarding causation." *Werderitsch v. Sec'y of Health & Human Servs*., No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005). Relying upon regulations found at 21 C.F.R. § 600.80, *Werderitsch* reasoned that because the Food and Drug Administration requires manufacturers to list adverse occurrences regardless of causality, the listing of an event on a product insert does not support a finding of causation. Other cases declining to rely upon package inserts to support a finding of causation include: *Salerno v. Sec'y of Health & Human Servs*., No. 16-1280, 2020 WL 344163, at *13 (Fed. Cl. Spec. Mstr. May 29, 2020); *Bender v. Sec'y of Health & Human Servs*., No. 11-693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. July 2, 2018) (noting that "vaccine package inserts do not constitute causation evidence meriting significant weight"), *mot. for rev. denied*, 141 Fed. Cl. 262 (2019); *Tompkins v. Sec'y of Health & Human Servs*., No. 10-261V, 2013 WL 3498652, at *14 (Fed. Cl. Spec. Mstr. June 21, 2013) (citing the testimony of petitioner's expert who acknowledged that reports in package inserts "may reflect a temporal relationship between vaccine and illness"), *mot. for rev. denied*, 117 Fed. Cl. 713 (2014); *Coppola v. Sec'y of Health & Human Servs*., No. 09-631V, 2012 WL 1118849, at *26 (Fed. Cl. Spec. Mstr. Mar. 7, 2012) (rejecting a petitioner's reliance on vaccine package insert information as indicative of alleged vaccine causation); *Doe v. Sec'y of Health & Human Servs*., No. 99-670V, 2004 WL 3321302, at *14 (Fed. Cl. Spec. Mstr. Oct. 5, 2004) (finding that petitioner failed to establish that hepatitis B vaccine can cause chronic fatigue syndrome although the package insert listed several symptoms petitioner experienced). *But see Russell v. Sec'y of Health & Human Servs*., No. 11-0282V, 2014 WL 4922194, at *7 (Fed. Cl. Spec. Mstr. Sept. 9, 2014) (giving some weight to a manufacturer's report of an adverse event "judged to be vaccine related by the study investigator" but still finding that petitioner failed to meet the burden regarding prong 1).

[68] *Supra*, note 37.

The mother also relied on the post-marketing adverse events contained in the insert for the Varivax vaccine. Pet. Ex. 54 at 3-4.[69] She acknowledged that the post-marketing adverse events are listed "*regardless of causality*." *Id*. (emphasis added). Thus, by her own admission, this evidence is insufficient to satisfy causation.

Further, the mother referenced "textbook" definitions for various mechanisms that have been associated with autoimmunity and how they can cause autoimmune diseases. Pet. Ex. 54 at 14-15, 23-24. However, she failed to provide how any of these mechanisms can be triggered by the varicella vaccine or can result in injury. She argued that the varicella vaccine contains MRC-5 and can cause autoimmunity but failed to provide any support for the mechanism by which this can occur. *Id*. at 15. While molecular mimicry, as well as bystander activation and epitope spreading, is a theory generally accepted in the Vaccine Program, a "simple invocation of the term generally does not carry a petitioner's burden of proof." *Deshler v. Sec'y of Health & Hum. Servs.*, No. 16-1070V, 2020 WL 4593162, at *20 (Fed. Cl. Spec. Mstr. July 1, 2020) (citing *Forrest v. Sec'y of Health & Hum. Servs.*, No. 14-1046V, 2019 WL 925495, at *3 (Fed. Cl. Spec. Mstr. Jan. 18, 2019)).

The mother relied on an article[70] that discusses a potential link between autoimmunity and severe mood and psychotic symptoms. Pet. Ex. 54 at 33-34. However, the study was in the context of autoimmune encephalitis—not vaccines. Petitioner did not have autoimmune encephalitis. Thus, the mother failed to provide a medical theory linking autoimmunity and severe mood and psychotic symptoms to any vaccine. *See generally id*.

The opinions provided in this matter are not sufficiently explained—by the mother or by any qualified expert[71]—to constitute preponderant evidence of causation. *See Doyle v. Sec'y of Health & Human Servs.,* 92 Fed. Cl. 1, 8 (2010) ("Mere conclusory opinions—or ones that are nearly so as unaccompanied by elaboration of critical premises—will not suffice as proof of causation, no matter how vaunted or sincere the offeror"). The mother claimed that "[m]uch data have been gathered that more than suggested a correlation between the petitioners (sic) immunodeficiency and her poor response to the live vaccine entering her body." Pet. Response at 26. Even if this claim were accepted, correlation does not amount to causation.

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[69] *Supra*, note 39.

[70] *Supra*, note 58.

[71] It should be noted that the mother is not qualified to render expert opinions on immunology or neurology. Though she stated she is a retired nurse, nothing in the records filed describes the mother's educational background or the area of medicine in which she practiced. This statement is in no way meant to attack the mother's intellect or diminish the importance of the nursing field. Rather, it is meant to highlight the reasoning behind affording more weight to Dr. Wiznitzer's opinions compared to the mother's opinions. Also important to my relative weighing of the opinions provided was that Dr. Wiznitzer's opinions were consistent with the medical records and objective testing, while the mother's opinions were not. But even if her opinions had been grounded in the medical records and supported by medical literature, her opinions would not be entitled to the same weight as a qualified expert such as Dr. Wiznitzer, who is a neurologist with years of education, completed several specialized fellowships over the span of a decade, is board certified, has extensive clinical experience, conducts research, and has been published in peer-reviewed journals and books. *See generally* Resp. Ex. B; *see also Gardner-Cook*, 59 Fed. Cl. at 48 (affirming a special master's finding that petitioner's expert was not "capable of offering an expert opinion on an alleged neuroimmunological disorder" when the expert had never practiced neurology).

For the foregoing reasons, petitioner has failed to provide a sound and reliable medical theory linking any of petitioner's alleged conditions to the varicella vaccine and has failed to prove prong I.

ii. Althen Prong II

The second *Althen* prong requires proof of "[a] logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccination can cause the injury alleged, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). However, petitioner's burden is not satisfied by treating providers' mere suspicion(s) that the subject vaccine caused petitioner's injury. *Fesanco v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 28, 34 (2011).

The mother argued that the varicella vaccine aggravated petitioner's "wiggling fingers . . . to the evolution of chorea athetosis tremor movement disorder, essential tremor." Pet. Response at 10. Significant aggravation of an injury requires additional analysis under *Loving*. *See Loving ex rel. Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009). However, there is no evidence of significant aggravation here. The contemporaneous medical records show that petitioner's hand tremors predated her receipt of the varicella vaccine. Pet. Ex. 2 at 14-15, 18, 43 (on July 2 2013, petitioner reported wiggling of her fingers to the pediatrician prior to her receipt of the varicella vaccine; on July 16, 2013, petitioner reported to Dr. McKean that she "started to have a tremor about 2 months ago"; on July 18, 2013, petitioner reported to Dr. Lacayo that she was "born with [the] symptoms" and it had been "lifelong"). There is no evidence in the medical records that petitioner's tremor worsened following the vaccine. Pet. Ex. 5 at 15 (initial examination with Dr. Lacayo did not reveal choreaform or athetotic movements and the tremor was unremarkable); Pet. Ex. 2 at 8 (Dr. Lacayo referred to her tics as associated with ADD with "the wiring of her brain [as] likely the cause of these features."); Pet. Ex. 12 at 5-8, 28-29 (Dr. Morgan documented "some ? chorea in her fingers with her arms outstretched" but the rest of the exam was not typical of chorea); Pet. Ex. 9 at 13-16, 37 (Dr. Silver noted a normal neurological exam with normal tone in December 2014, but "there could sometimes be an underlying tremulous feeling coming and going in her arms, hard to tell if it was voluntary or not; Dr. Helmers noted a normal neurological exam in August 2015 with involuntary movements "present when asked to show tremor."). Thus, even if petitioner had provided a reputable medical theory showing that a varicella vaccine could worsen an unremarkable essential tremor, her clinical history does not show that this occurred.

Further, the mother argued that the varicella vaccine "reactivate[ed]" HHV-6. Pet. Response at 8; Pet. Ex. 54 at 13. In August 2015, two years post-vaccine, petitioner's lab work showed HHV-6 IgG antibodies. Pet. Ex. 14 at 4. The lab work does not show when she was exposed to the virus or that it was "reactivated." *See id*. Dr. McKean documented the results as "suggest(ing) that her fatigue may be due to chronic HHV-6 infection"; but nothing in his record

reflects that Dr. McKean believed there was a link between petitioner's HHV-6 positive lab work and the varicella vaccine she received in 2013. Pet. Ex. 4 at 6. Therefore, petitioner failed to provide any persuasive evidence that the varicella vaccine can reactivate HHV-6 or did so in petitioner.

Finally, the mother claimed that petitioner's mood and neurocognitive disorders were caused by the varicella vaccine. Pet. Response at 3-4. This claim—absent a reputable medical theory and supportive evidence—is insufficient to meet petitioner's burden. Of note, Dr. Dyer's assessment roughly three weeks after the vaccine included learning disabilities and anxiety disorder. An assessment a year later, in August 2014, included decline in cognitive functioning and evidence of a neurocognitive disorder. *See generally* Pet. Ex. 6. Both assessments were based in large part on history provided by the mother and petitioner, which included events they claimed occurred following petitioner's receipt of the varicella vaccine. To that end, Dr. Dyer wrote, "there is evidence that suggests a causative link between vaccinations and periods of cognitive decline." *Id*. at 1, 6, 10. However, she did not specify the evidence she believed supported this opinion. Similarly, Dr. Helmers at Emory recommended a neuroimmunology evaluation "since [the psychiatric] and neurologic symptoms may be related to the varicella booster"; this recommendation was based on a medical history provided by the mother that evolved over time and included many inaccuracies, including an anaphylactic reaction three days after varicella vaccine, seizure at age 16, ongoing cluster seizures, and "staring off" over the past 6-12 months. Pet. Ex. 9 at 2, 4-5.

The mother is undoubtedly an involved and devoted parent. However, she is not a reliable narrator of petitioner's medical history. The medical records show that the mother and petitioner frequently reported that petitioner had diagnoses that were either not mentioned in the records or were ruled out by objective testing and clinical presentation. Dr. Dyer's and Dr. Helmers' conclusions were based on inaccurate or unsubstantiated reporting from the mother and petitioner and on the timing of petitioner's alleged symptoms after receipt of the varicella vaccine, all insufficient to prove causation. *Balasco v. Sec'y of Health & Human Servs*., No. 17-215V, 2020 WL 1240917, at *21 (Fed. Cl. Spec. Mstr. Feb. 14, 2020) (rejecting statements from treating doctors about diagnosis when the treaters relied upon history that was not correct); *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("When a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury. To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury."). Neither doctor explained how the vaccine caused petitioner's alleged symptoms, only that petitioner's reported symptoms raised suspicion that the vaccine was the cause based on the mother's medical history and a temporal relationship which is insufficient to meet petitioner's burden. *Fesanco*, 99 Fed. Cl. at 34.

Similarly, Dr. Lacayo wrote that he was unsure whether the vaccine was the cause of petitioner's symptoms, adding that "the timing of such with her seems to have aggravated her condition, with history of the same in the past." Pet. Ex. 2 at 8. Dr. Lacayo did not specify what symptoms he thought were caused or aggravated by the subject vaccine but admitted that petitioner's medical history came from discussions with the mother. Pet. Ex. 6 at 2; Pet. Ex. 7a at 6; Pet. Ex. 8 at 16; Pet. Ex. 9 at 8; Pet. Ex. 12 at 5, 10, 25, 28. Despite arguments to the contrary,

no evidence in the medical records shows that petitioner suffered reactions following two MMR vaccines at 21 months and age 5 or following her first varicella vaccine at age 11. Pet. Ex. 15 at 3; Pet. Ex. 16 at 3. The mother only began reporting adverse reactions to those vaccines to medical providers after petitioner received the subject varicella vaccine at age 16. Thus, much like Dr. Dyer's and Dr. Helmers' opinions, Dr. Lacayo's statements are similarly flawed as he relied on inaccurate—or at least unsubstantiated—reports of petitioner's medical history. Further, Dr. Lacayo's conclusion is based on timing alone, which is insufficient to show a logical sequence of cause and effect.

The remaining diagnoses alleged are best addressed under prong III. Based on the foregoing, petitioner failed to provide a logical sequence of cause and effect between the varicella vaccine and her various conditions and failed to satisfy prong II.

iii. Althen Prong III

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

In general, petitioner alleged a host of conditions, injuries, and/or illnesses she argues are causally related to the varicella vaccine she received on July 2, 2013. Most were ruled out by objective testing and others are discussed in detail above. The remaining conditions discussed below fail to satisfy *Althen* prong III because they either pre-dated the vaccine or were too remote in time to have been related to the vaccine.

Petitioner's records contain details of ongoing psychological and behavioral issues throughout her childhood along with, or as a result of, her learning disabilities, attention deficits, and visual issues. Over the years, she has been diagnosed with anxiety, depression, and an unspecified mood disorder. It is unclear, and there was no medical expert report filed to explain, how her anxiety, depression, and mood disorder relate to her childhood psychological and behavioral issues or if they are one and the same and simply referred to differently in her teen years and adulthood than when she was a child. However, the medical and school records document the presence of these issues since petitioner was a young child. *See* Pet. Ex. 6; Pet. Ex. 20 at 14-15; Pet. Ex. 22 at 2; Pet. Ex. 23 at 2; Pet. Ex. 25 at 7-9; Pet. Ex. 26 at 1; Pet. Ex. 15 at 7-9.

More specifically, Dr. Cates discussed petitioner's "extreme behavior changes" dating back to 2003. Pet. Ex. 26 at 1; *See* Pet. Ex. 28: Pet. Ex. 29; Pet. Ex. 30; Pet. Ex. 31. The mother completed a health questionnaire in December 2005, documenting that petitioner had "behavioral + academic issues" that were "managed through routine, diet and a customized IEP". Pet. Ex. 15 at 7-9. Initially, following petitioner's receipt of the subject varicella vaccine, the mother reported that petitioner had a sore throat, trouble swallowing, choking sensation, and "feeling vaguely ill for a couple of weeks." There was no mention of abnormal behavior or mood changes. Pet. Ex. 2 at 24. Petitioner underwent psychological evaluation with Dr. Dyer three weeks after receipt of the varicella vaccine "to evaluate cognitive and academic functioning" for entry to school in the fall. *Id*. at 10. Though the examination itself took place shortly after the vaccine was received, the results were in part based on petitioner's background and medical history since birth, which included delayed comprehension and academic struggles since pre-kindergarten as reported by the mother. *Id*. at 10-11. The mother also reported petitioner's history of difficulties with tasks and following directions, being easily angered and defiant, struggling to control negative moods, and being worrisome. *Id*. at 11. Many of these concerns dated back to 2004. Pet. Ex. 15 at 8; Pet. Ex. 17 at 7; Pet. Ex. 18 at 1. However, neither petitioner nor the mother reported behavioral changes that manifested after the vaccine. Thus, consistent with the history provided by the mother, petitioner had behavioral issues for years prior to her receipt of the vaccine and, as such, they are unrelated to the vaccine.

Two years after the subject vaccine, in June 2015, petitioner was diagnosed with major depressive disorder by Dr. Richardson. Pet. Ex. 13 at 3-4. It is not clear from the records filed when her symptoms of depression began. During the evaluation with Dr. Richardson in June 2015, the mother repeated many of the complaints she made during Dr. Dyer's evaluation in July 2013 which included a history of rebellion, aggression, and being combative. *Id*. at 3. However, petitioner described herself to Dr. Richardson as having feelings of hopelessness, self-punishment, and internalization of other's negative attitudes. The diagnosis was severe depressive disorder. *See generally id*. In April of 2014, petitioner's parents had her admitted to Ridgeview Institute for erratic behavior and angry outbursts. At that time, petitioner described herself as having moderate anxiety, feelings of hopelessness, trouble sleeping and eating, and mood swings. Pet. Ex. 7a at 6-7. She reported significant discord with her parents and was "[f]ixated" on getting her parents' approval. *Id*. at 7. During her time at Ridgeview Institute, she was described as polite and cooperative without any out-of-control behavior noted on admission or on the unit. *See generally id*. Based on the records, it is not clear whether petitioner had symptoms of depression prior to the vaccination or whether they manifested only after the vaccination.[72] To the extent that symptoms manifested after the vaccine, they were first documented nearly one year after receipt of the varicella vaccine and not again until roughly two years following vaccination. Accordingly, onset of major depressive disorder was far too remote in time to be associated with the varicella vaccine.

Further, a paraneoplastic panel ordered by Dr. Silver on March 26, 2015, showed antibodies to AChR. However, petitioner was not diagnosed with MG at that time because she was asymptomatic. Pet. Ex. 9 at 23, 25, 29, 34. Three years later, in March 2019, Dr. Rivner diagnosed

[72] No records were filed for the timeframe between 2011 and 2013, and the mother stated petitioner did not require medical care during that time. Pet. Ex. 35 at 5-6. Based on petitioner's medical history with extensive testing and frequent appointments, as well as the mother's vigilance with petitioner's health, it is hard to reconcile a two-year period with no medical care at all.

petitioner with MG despite atypical symptoms. Pet. Ex. 38 at 1-3. Petitioner failed to provide a medically reasonable timeframe for which, given the medical understanding of autoimmune diseases, causation could be inferred. *de Bazan*, 539 F.3d at 1352; *Pafford*, 451 F.3d at 1358. I find it difficult to accept that the manifestation of disease six years after vaccination is a medically reasonable timeframe to implicate the vaccine as the cause. Still, it is unknown if the AChR antibodies were present prior to the subject vaccine or arose several years after receipt of the vaccine when it was tested. Petitioner's diagnosis of MG is too remote in time to infer a proximate temporal relationship with the vaccine.

Likewise, petitioner argued that she is immunodeficient. It is unclear whether petitioner is submitting that the varicella vaccine caused petitioner's injuries because she was immunodeficient or whether the vaccine caused her immunodeficiency itself. Pet. Ex. 54 at 1-3; Pet. Resp. at 4-5. Nevertheless, petitioner failed to provide any persuasive evidence to support either claim. Her immunodeficiency was diagnosed in March 2016—nearly three years after she received the varicella vaccine. Pet. Ex. 4 at 2. It is certainly possible for symptoms of a condition to present prior to receiving a diagnosis. However, petitioner did not point to any evidence to prove that she was immunodeficient prior to receiving the vaccine.

In sum, petitioner failed to provide persuasive evidence to show a proximate temporal relationship between the varicella vaccine and any of the conditions she suffered. Petitioner failed to satisfy *Althen* prong III.

VI. Conclusion

Petitioner has suffered many challenges throughout her life. Despite my sincere sympathy for what petitioner has endured, my decision must reflect a thorough analysis, showing that I weighed the evidence presented and applied the law. After thoroughly reviewing all the medical and other records filed, expert reports and letters, medical literature, and submissions of both parties, it is clear that petitioner has failed to provide sufficient evidence to demonstrate that the varicella vaccine can cause or did cause any of the injuries petitioner has alleged or that it did so within a medically reasonable timeframe in order to satisfy the *Althen* criteria.

For these reasons, I find that petitioner has not established entitlement to compensation and her petition must be **dismissed.**[73] In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment consistent with this decision.[74]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[73] Respondent's Motion to Dismiss filed on January 6, 2017 is hereby rendered moot. *See* ECF No. 61.
[74] Pursuant to Vaccine Rule 11(a), if a motion for review is not filed within 30 days after the filing of the special master's decision, the Clerk will enter judgment immediately.